  
70552-1



  
009242503



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg.  
Number:

Date of Issuance:

5/19/2005

70552-1

Term of Issuance:

Conditional

Name of Pesticide Product:

Paraquat Technical  
Concentrate

NOTICE OF PESTICIDE:  
X Registration  
— Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sinon Corporation  
111, Chung-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

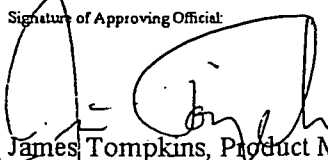
On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided you agree in writing to:

1. Submit the following: guideline 830.6317 (One Year Storage Stability Study) and guideline 830.6320 (Corrosion Characteristics Study) within one (1) year from the date of this registration letter.
2. Change EPA Reg. No. on label from 70552-R to 70552-1.
3. Remove "Refer to the booklet 'Paraquat Poisoning. A Practical Guide to Diagnosis, First Aid and Hospital Treatment'. (<http://syngenta.com/pqmedguide>)." from the NOTE TO PHYSICIAN statement.
4. Remove "Open dumping is prohibited" from directly under the STORAGE AND DISPOSAL header, and move to under the subsection PESTICIDE DISPOSAL.

Signature of Approving Official:

  
James Tompkins, Product Manager (25)  
Herbicide Branch, Registration Division (7505C)

Date:

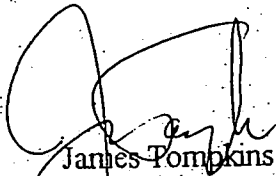
5/19/2005

Signed 9:00 am

Please note that Agency approval of the label should not be construed as a decision by the Agency that the language on the Warranty Statement is not misleading.

You will submit one (1) copy of your final printed labeling before you release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). A stamped copy of labeling is enclosed for your records.

If you have any questions, please contact Hope Johnson at 703-305-5410.



James Tompkins  
Product Manager (25)  
Herbicide Branch  
Registration Division (7505C)

## Paraquat Technical Concentrate

For Formulation of Paraquat Herbicide Products Only

|                                                                         |        |
|-------------------------------------------------------------------------|--------|
| ACTIVE INGREDIENT                                                       |        |
| Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride) ..... | 46.2%  |
| INERT INGREDIENTS .....                                                 | 53.8%  |
| TOTAL .....                                                             | 100.0% |

Contains 3.16 pounds paraquat cation per gallon  
Contains emetic.

EPA Reg. No. 70552-R

EPA Establishment No. 70552-TWN-001

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER - PELIGRO**



**POISON**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

MAY 19 2005

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

70552-1



| <b>FIRST AID</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <ul style="list-style-type: none"> <li>• <b>SPEED IS ESSENTIAL.</b> Immediate medical attention is required. If available, give an adsorbent such as activated charcoal, bentonite or Fuller's Earth.</li> <li>• Call a poison control center or doctor immediately for treatment.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                                  |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 to 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>                                                                                                                          |
| If Inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance.</li> <li>• Call a poison control center or doctor for further treatment advice</li> </ul>                                                                                                                                    |
| <b>NOTE TO PHYSICIAN</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                  |
| <p>Refer to the booklet 'Paraquat Poisoning. A Practical Guide to Diagnosis, First-Aid and Hospital Treatment'. (<a href="http://www.syngenta.com/pqmedguide/">http://www.syngenta.com/pqmedguide/</a>) Administer either activated charcoal (100g for adults or 2g/kg body weight in children) or Fuller's Earth (15% solution; 1 liter for adults or 15mg/kg body weight in children).</p> <p>NOTE: The use of gastric lavage without administration of an adsorbent has not shown any clinical benefit. Do not use supplemental oxygen. Eye splashes from concentrated material should be treated by an eye specialist after initial treatment. With the possibility of late onset corneal ulceration, it is advised that patients with paraquat eye injuries are reviewed by an eye specialist the day after first presentation. Use treatment that is appropriate for chemical burns. Intact skin is an effective barrier to paraquat, however contact with irritated or cut skin or repeated contact with intact skin may result in poisoning.</p> |                                                                                                                                                                                                                                                                                                                                                                  |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                  |
| <b>HOTLINE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                  |
| For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                  |

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER – POISON**



May be fatal if swallowed. Fatal if inhaled. Do not breathe spray mist. Do not inhale contaminated dust. Causes irreversible eye damage. Wear [goggles, face shield, or safety glasses]. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin.

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
  - Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)
  - Full face shield
  - Chemical-resistant gloves, Category A
  - Chemical resistant apron and shoes plus socks
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

**ENVIRONMENTAL HAZARDS**

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

**PHYSICAL AND CHEMICAL HAZARD**

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

**SPILLAGE DURING TRANSPORT**

**Emergency Action:** Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

**KEEP PUBLIC AND ANIMALS** away from area. **MARK ROADS AND WARN OTHER ROAD USERS.** WEAR face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into a herbicide for the following uses:

### (1) TERRESTRIAL FOOD CROP

acerola (West Indies cherry); apricot; asparagus; avocado; banana; blackberry; blueberry; boysenberry; broccoli; cabbage; cabbage, Chinese; carrot (including tops); cauliflower; cherry; cocoa; coffee; collards; cucumber; eggplant; fig; filbert (hazelnut); garlic; groundcherry (strawberry tomato/tomatillo); guava; hops; kiwifruit; lettuce; loquat; macadamia nut (bushnut); manioc (cassava); melons; melons, cantaloupe; melons, musk; melons, water; mint; nectarine; olive; onion; papaya; passion fruit; peach; pear; pecan; pepino (melonpear); pepper; pepper (chili type); pineapple; pistachio; plum; potato, white/Irish; prune; pumpkin; raspberry (black, red); rhubarb; smallfruits; squash (all or unspecified); strawberry; sugarbeet; taro; walnut (English/black); yam; yautia

### (2) TERRESTRIAL FOOD+FEED CROP

almond; apple; barley; beans, asparagus; beans, dried-type; beans, mung; beans, succulent (lima); beans, succulent (snap); citrus fruits; corn (unspecified); corn, field; corn, pop; corn, sweet; cotton (unspecified); garbanzos (including chickpeas); grapes; guar; hops; legume vegetables; mint; oats; orchards (unspecified); peanuts; peanuts (unspecified); peas (unspecified); peas, field; peas, pigeon; peppermint; potato, white/Irish; safflower; safflower (unspecified); small fruits; small grains (unspecified); sorghum; sorghum (unspecified); soybeans (unspecified); soybeans, edible; spearmint; sugarbeet; sugar crops; sugarcane; sunflower; tomato; turnip; vegetables (unspecified); wheat

### (3) TERRESTRIAL FEED CROP

alfalfa; barley; beans; clover; crownvetch; legume vegetables; lespedeza; lupine; pastures; sainfoin; timothy; trefoil; tyfon; vetch; wheat

### (4) TERRESTRIAL NON-FOOD CROP

agricultural fallow/idleland; airports/landing fields; commercial/industrial lawns; commercial/institutional/industrial; premises/equipment (outdoor); fencerows/hedgerows; grasses grown for seed; industrial areas (outdoor); jojoba; nonagricultural outdoor buildings/structures; nonagricultural uncultivated areas/soils; ornamental and/or shade trees; peach (non-bearing, seed beds); recreation area lawns; tomato (post-harvest); wood protection treatment to forest products (seasoned)

### (5) FORESTRY

forest plantings (reforestation programs); pine (forest/shelterbelt); shelterbelt plantings

**(6) TERRESTRIAL NON-FOOD**

ornamental and/or shade trees; ornamental herbaceous plants;  
ornamental woody shrubs and vines; non-crop areas such as public  
airports, electric transformer stations and around commercial buildings

**(7)** Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted  
in support of registration; and

**(8)** Uses for experimental purposes that are in compliance with USEPA requirements.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

**WARRANTY STATEMENT**

SINON CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by Buyer and User. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this product. SINON CORP. makes no warranties of merchantability or of fitness for a particular purpose nor for any other expressed or implied warranty except as stated above.

Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 04-19-2005. NOT EPA APPROVED

70552-R

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January 23, 2004

Patricia A. Roberts  
Associate General Counsel for  
Pesticides and Toxic Substances  
Office of the General Counsel  
U.S. Environmental Protection Agency  
Ariel Rios Building, Mail Code 2333A  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460

Re: Petition to Deny Sinon Corporation's Application to Register Paraquat Technical Concentrate

Dear Ms. Roberts:

Syngenta Crop Protection, Inc. (Syngenta) hereby petitions the Environmental Protection Agency (EPA or the Agency) to deny Sinon Corporation's (Sinon's) application to register the pesticide product Paraquat Technical Concentrate containing the active ingredient paraquat dichloride (paraquat). Syngenta brings this Petition under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y, as amended, EPA's FIFRA regulations, including 40 C.F.R. Part 152, the Petition Clause of the First Amendment, and the Administrative Procedure Act, 5 U.S.C. § 555(b). Syngenta currently holds the only registrations for paraquat in the United States that are not based on the formulator's exemption, owns all the paraquat data that support registration, is the only company conducting the testing necessary to maintain registrations of paraquat, and is the only company investing in stewardship to continually improve the safety of paraquat.

This petition is different from most petitions EPA reviews because of unusual factual issues related to the applicant's fitness to hold the registration it seeks and an important threshold legal issue as to the sufficiency of the "notice of intent" that Sinon seeks to employ as the basis to request EPA review of its application.

There are three principal reasons EPA should deny Sinon's application:

First, publicly-available information suggests that Sinon may have begun shipping unregistered paraquat from Taiwan to the United States for domestic use in violation of FIFRA. Sinon may also have knowledge that the purchaser of at least a significant portion of this

Jim  
Make sure we do  
not register w/o  
discussing internally  
w/ doc

Let me  
know  
when  
we  
sit f.  
it.  
Don

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paraquat, Marman USA, Inc. (Marman), a Tampa, Florida-based pesticide company, may have misled EPA and foreign officials about Marman's commercial trade in purported existing stocks of a long-cancelled paraquat formulation by Zeneca Ag Products Inc.<sup>1</sup> If, upon further investigation, EPA finds that Sinon has exported to the United States unregistered pesticide intended for domestic use, or that Sinon has provided freshly produced paraquat to Marman for sale abroad under the guise of "gold seal" letters that Marman obtained from EPA for trade in existing stocks, EPA may deem Sinon unfit to hold the desired registration and deny Sinon's application. See EPA, *Termilind Limited; Notice and Order of Revocation of Registrations*, 62 Fed. Reg. 61890 (Nov. 19, 1997) (revoking registration based on registrant's false statements regarding its foreign source of unregistered technical product).<sup>2</sup>

Second, to fully rely on Syngenta's data, Sinon must prove, through an EPA comparison of Syngenta's data with Sinon's product chemistry and acute toxicity data on the actual product Sinon wishes to sell in the United States, that the paraquat Sinon seeks to sell in the United States is substantially similar to Syngenta's. Syngenta has been a dedicated steward of paraquat, and has continually worked to produce paraquat that is as pure as possible in a manner that is as safe as possible. Syngenta is not supplying paraquat to Sinon and is not aware of any other manufacturer of paraquat that uses the same processes as Syngenta. Nor is Syngenta aware of any other company producing paraquat end-use products employing the safety features in Syngenta's products.

Third, the only data submitted to EPA that are sufficient to support an application such as Sinon's are data owned by Syngenta. However, Sinon admits that it has not made any offer to pay compensation to Syngenta for reliance on those data. Without such an offer, Sinon may not rely on Syngenta's data, its application is incomplete, and EPA should deny it.

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<sup>1</sup> Zeneca Ag Products Inc., together with Novartis Crop Protection, Inc., became Syngenta Crop Protection, Inc. in 2000.

<sup>2</sup> Syngenta understands that Marman views these issues differently. See Letter from K. Sherman, Syngenta, to R. Renes, Marman (December 8, 2003); Letter from R. Renes, Marman, to K. Sherman, Syngenta (January 19, 2004); Syngenta also is providing to Marman a courtesy copy of today's petition. However, the publicly-available facts raise serious concerns that go to the heart of EPA's pesticide regulatory oversight. The government has the ability and responsibility to obtain and review the underlying facts to ensure that all pertinent laws and regulations are being respected under circumstances such as those present here.

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## **I. BACKGROUND**

### **A. Registration History of Paraquat**

Paraquat was first registered for use in the United States in 1964. Over its four decades of use, paraquat has developed a strong record of providing excellent non-selective weed control and benefits to the environment through soil conservation, and has become one of the world's most widely-used herbicides. This achievement rests on the work of Syngenta and the high regulatory standards upheld by EPA. Today Syngenta is the sole product steward of paraquat in the United States, the owner of all the data that support registration, and the only company committed to generating the data required by EPA to maintain paraquat registrations. Other companies periodically have registered products containing paraquat over the years, but all of the companies except Syngenta have decided not to defend the product.

Paraquat is registered for numerous uses, involving diverse exposure settings, underscoring the importance of rigorous adherence to registration standards for this foundation herbicide. A non-specific contact herbicide, paraquat is registered to control weeds and grasses in a variety of agricultural and non-agricultural areas. Agricultural uses of paraquat include cotton, fruits, grains, peanuts, potatoes, soybeans, sugar cane, and vegetables. Non-agricultural use is principally for weed control around public airports, electric transformer stations, and commercial buildings.

EPA issued a Registration Standard for paraquat in June 1987, followed by a Data Call-In (DCI) in December 1991. The 1991 DCI required submission of ecological effects, environmental fate and residue chemistry data. Paraquat was declared eligible for reregistration in EPA's August 1997 Reregistration Eligibility Decision (RED). Syngenta was at that time, and is today, the sole non-formulator's exemption registrant of paraquat. EPA's August 1997 RED for paraquat was accompanied by a DCI requiring submission of additional data in the following areas: product-specific product chemistry, general product chemistry, acute toxicity, residue chemistry, and spray drift. Syngenta has consistently addressed EPA's data requirements.

Throughout this history, Syngenta has invested, and continues to invest, significantly in product stewardship to continually improve the safety of paraquat.

### **B. Syngenta is Filing This Petition to Protect Its Rights Under FIFRA**

Syngenta's Petition is prompted by Sinon's letter of intent to apply for a registration of the pesticide product "Paraquat Technical Concentrate". Letter from E. Brown, ChemReg International, LLC, Registration Agent for Sinon, to Syngenta (Oct. 14, 2003) (enclosed as Exhibit 1). The letter states that Sinon intends to cite in support of Sinon's application data that were originally submitted to EPA by Syngenta, but admits that Sinon has not made an offer to pay. *Id.*

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Syngenta is entitled to petition EPA to deny Sinon's application pursuant to FIFRA Section 3(c)(1)(F) and the supporting regulations at 40 C.F.R. Part 152. Syngenta is a current registrant of paraquat technical, and sole owner and original submitter of the vast majority of the studies that satisfy paraquat data requirements. As an original data submitter of studies that satisfy data requirements that Sinon has not satisfied, and lacking an offer from Sinon to pay compensation for Sinon's reliance on Syngenta's data, Syngenta is entitled to bring this Petition. 40 C.F.R. § 152.99(a)(2).

In addition to a data submitter's specific rights under 40 C.F.R. § 152.99, EPA has recognized its obligation to give due consideration to Petitions to Deny pursuant to the Petition Clause of the First Amendment to the United States Constitution. *See, e.g.,* Letter from J. Jones, Director, Registration Division, Office of Pesticide Programs, EPA, to J. Wright and J. Liss (June 13, 2000).

Syngenta also is entitled to petition EPA under the Administrative Procedure Act (APA), 5 U.S.C. § 555(b), which provides:

So far as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function.

*Id.*; *see also Block v. Securities & Exchange Commission*, 50 F.3d 1078, 1085 (D.C. Cir. 1995) (noting that Section 555(b) of the APA "is universally understood to establish the right of an interested person to participate in an ongoing agency proceeding").

If facts of the type set forth below are confirmed, EPA must deny Sinon's application on fitness-for-registration grounds. EPA must also deny Sinon's application absent a demonstration that Sinon is entitled to rely on Syngenta's data through a showing of substantial similarity, and absent a proper offer to pay compensation to Syngenta for Sinon's reliance on Syngenta's data, furnished at the appropriate time. EPA is obligated to ensure that these standards and requirements are met before granting a registration to Sinon, and, in the case of an offer to pay, EPA must require that it be furnished to Syngenta before EPA may consider Sinon's application.



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## II. ARGUMENT

### A. *Sinon May be Unfit to Hold a Paraquat Technical Registration*

Recent large exports of paraquat by Sinon to the United States, possibly in violation of FIFRA, may warrant denial of Sinon's application based on fitness concerns. EPA has recognized that "as a general matter, determining the 'fitness' of an applicant to hold a license or registration is . . . a legitimate end of licensing schemes." EPA, *Termilind Limited; Notice and Order of Revocation of Registrations*, 62 Fed. Reg. 61890, 61893 (Nov. 19, 1997). Moreover, "prior to granting a [pesticide] registration, the Agency is *required* to determine that a pesticide will not 'generally cause unreasonable adverse effects on the environment' when used in accordance with wide-spread and commonly recognized practice." *Id.* (citing FIFRA Section 3(c)(5)(D)) (emphasis added). "[T]he integrity or reliability of a registrant is highly germane to the Agency's ability to make an accurate finding; if the Agency has reason to suspect that materials submitted by a registrant are untrustworthy, an affirmative safety finding cannot be made." *Id.* Consequently, a "'fitness' or 'reliability' [of the applicant] criterion can . . . be implied as a component of the 'unreasonable adverse effects' standard." *Id.*

In the *Termilind* case, EPA cited fitness concerns as the basis for revoking Termilind's end-use and technical registrations for naphthalenaecetic acid (NAA) products. EPA found that Termilind acted fraudulently when Termilind cited Amvac Chemical Corporation (Amvac) as the source of Termilind's technical NAA active ingredient, when in fact Amvac had never sold any technical NAA to Termilind. Termilind was instead selling pesticide products formulated with unregistered NAA and imported by a South Korean company. With limited exceptions not pertinent here, the importation of unregistered pesticides other than for export is unlawful. See FIFRA Section 17; PR Notice 99-1, *Import of Unregistered Pesticides Intended for Export* (Mar. 1, 1999). The scheme had gone unnoticed by EPA because Termilind also failed timely to submit to EPA the required Notice of Arrival of Pesticides and Devices pursuant to FIFRA Section 17 and U.S. Customs regulations at 19 C.F.R. § 12.112.

Before registering another source of technical grade paraquat, EPA must satisfy itself that Sinon is not participating in the importation of unregistered pesticide intended for domestic use and is not complicit in misleading EPA and foreign officials concerning the technical source of Marman's paraquat products marketed abroad. As discussed below, the large volumes of Sinon paraquat product already entering the United States raise a host of FIFRA compliance issues.

Marman has represented to the EPA that it continues to have existing stocks of Zeneca's 43.5% paraquat, a pesticide that Zeneca last sold to Marman seven years ago and that EPA cancelled over five years ago. Marman's trade in paraquat is predicated upon Zeneca's cancelled registration. EPA records dating as far back as October 1998 indicate that EPA permitted Marman to conduct trade in 43.5% paraquat on the condition that Marman limit its activities to repackaging any remaining existing stocks of Zeneca's long since cancelled product, pursuant to

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FIFRA's narrow formulator's exemption, FIFRA Section 3(c)(2)(D). *See* Letter from K. Davis, RegWest Company (regulatory agent for Marman), to J. Tompkins, Product Manager, Office of Pesticide Programs, EPA (Oct. 30, 1998); Letter from J. Tompkins to K. Davis (Oct. 19, 1998) (enclosed together as Exhibit 2). It appears that Marman may have been misleading government officials at EPA and abroad with respect to its holdings of such existing stocks and may be engaged in unlawful imports and exports of paraquat from an unregistered source or sources, such as Sinon. *See* FIFRA Section 17; *see also* 40 C.F.R. § 152.85 (Formulator's Exemption) (among other requirements, product must be "derived solely from one or more EPA-registered products which [are purchased] from another producer").

As recently as March 2002, Marman advised EPA that it held existing stocks of Zeneca's old product and continued to rely on Marman's October 19, 1998 Confidential Statement of Formula. *See* Letter from K. Davis to J. Tompkins (Mar. 22, 2002); Letter from J. Tompkins to K. Davis (Aug. 28, 2000); Letter from M. Novak (counsel for Marman) to J. Jones, Director, Registration Division, Office of Pesticide Programs, EPA (June 22, 2000); Letter from J. Tompkins to K. Davis (Mar. 27, 2000); Letter from K. Davis to D. Stubbs, Chief, Herbicides Branch, Office of Pesticide Programs, EPA (Mar. 13, 2000) (enclosed together as Exhibit 3). Because Zeneca ceased supplying Marman with paraquat seven years ago, it is unlikely that Marman possesses existing stocks that support Marman's ongoing commercial trade in paraquat, particularly given the quantities involved, as discussed below.

According to publicly-available information, from November 2001 to July 2003, Sinon and another company located in Taiwan, Camfall, exported over 750,000 pounds of paraquat to the United States for Marman. *See* Exhibit 4, Marman Paraquat Imports into the United States: November 2001-July 2003. During 2002, Marman re-exported approximately 85,000 pounds to Caribbean port locations and apparently destined for South and Central American markets. *See* Exhibit 5, Marman Paraquat Exports from the United States to Caribbean Ports: January-December 2002. Syngenta understands that Marman paraquat products are offered for sale in these markets, and that the labeling in these countries states that the products are produced in the United States.

Marman apparently conducts this trade through the use of "gold seal" letters obtained from EPA. *See, e.g.,* Requests for Certificate of Product Registration of R. Renes, Vice President, Marman (July 19 and Nov. 27, 2001), and Sept. 18, 2001 and Jan. 24, 2002 EPA gold seal letters (enclosed together as Exhibit 6). Marman apparently uses these letters to assure trading partners of the United States that Marman's product is properly registered with EPA, and may be marketed and sold in the United States. It appears very unlikely, however, that Marman actually is repackaging Zeneca-manufactured, U.S. labeled 43.5% pesticide product to support its activities.

Marman may be selling Sinon's paraquat as a Zeneca product with the appearance of EPA approval, notwithstanding that Sinon's paraquat has not been reviewed and approved by

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EPA under FIFRA Section 3. Based on publicly-available import records, most of Marman's imports appear to arrive at either Savannah, Georgia or Charleston, South Carolina ports. *See* Table at Exhibit 4. Syngenta has no basis to believe that these volumes were historically produced and labeled as a Zeneca product. Rather, it is reasonable to conclude that this is all or substantially all *freshly-produced* product in bulk containers from one or more manufacturers not registered by EPA, such as Sinon, in violation of the terms of Marman's registration and contrary to its statements to EPA. Syngenta has expressed its concerns to Marman and understands that Marman does not agree with these concerns. *See supra* n.2.

Claims by Marman that its product complies with United States requirements raise specific concerns with respect to Sinon's exports of paraquat to Marman. Sinon's paraquat currently is unregistered and, under the circumstances here, its importation into the United States is permissible only if it is intended for export. *See* FIFRA Section 17; PR Notice 99-1. Before an unregistered pesticide or active ingredient may be exported to the United States, it must be formulated according to the specifications of an identified foreign purchaser. *See* FIFRA Section 17(a)(1). The producer of such pesticides and active ingredients must also comply with certain recordkeeping, establishment registration, and labeling requirements under FIFRA. *See id.* For example, the producer must incorporate into the pesticide label the statement, "Not Registered for Use in the United States of America." *See* FIFRA Section 2(q)(1)(H). A signed acknowledgement must be obtained from the foreign purchaser that the pesticide is not for use or sale in the United States. *See* FIFRA Section 17(a)(2). A Notice of Arrival of Pesticides and Devices must be submitted to EPA before the shipment reaches port. *See* FIFRA Section 17(c); 19 C.F.R. § 12.112. Upon lawful release by Customs, the shipment must be transported directly to a registered pesticide establishment, which in turn must file a report with EPA identifying the activity in which it is engaging, such as reformulation, relabeling, or distribution. *See* FIFRA Section 7; PR Notice 99-1.

Beginning in May 2003, Sinon appears to have become Marman's sole provider of paraquat. *See* Table at Exhibit 4. Of the approximately 185,000 pounds of paraquat imported by Marman from Sinon since that time, approximately 60,000 pounds do not appear to have been re-exported. If Marman has been purchasing unregistered paraquat from Sinon in anticipation of Sinon's receipt of a registration and without intent to re-export it, both Marman and Sinon may be in violation of FIFRA Section 17. Moreover, according to EPA, Marman lacks an active EPA Establishment Number under FIFRA Section 7. *See* E-mail from C. Buckingham, Office of Enforcement and Compliance Assurance, EPA, to S. Waynick, Syngenta (Jan. 15, 2003) (enclosed as Exhibit 7). Under these circumstances, Marman does not have the basis on its own to conduct the minimal activities of re-labeling and re-packaging paraquat for export in the first instance. While it is possible that such activities are being conducted by an EPA-registered establishment, there is no apparent record demonstrating this.

A responsible registrant or product steward would not export large volumes of an unregistered pesticide to the United States without taking steps to ensure that it complies with the

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requirement that its product is destined for re-export. A responsible registrant or product steward would also be expected to seek assurance that the purchaser of its product is lawfully permitted to conduct the business it proposes to carry out with that product.

The facts provided above should have served as a signal to Sinon that its arrangement with Marman may have been improper. In addition, Marman's use of gold seal letters to export what appears to be unregistered paraquat is directly contrary to the requirement of FIFRA Section 2(q)(1)(H) that unregistered pesticides bear a label stating that it is "Not Registered for Use in the United States of America." If these or other requirements of FIFRA were not met, Sinon likely knew or perhaps should have known that it was involved in an inappropriate arrangement to import unregistered paraquat into the United States.

These facts raise serious questions about Sinon's compliance with its statutory obligations under FIFRA, its possible complicity in Marman's apparently false statements to EPA and foreign officials, and, consequently, Sinon's fitness to hold the registration it seeks. The Agency should resolve these issues before granting a registration to Sinon to manufacture and sell one of the country's major herbicides.<sup>3</sup>

***B. Sinon Must Demonstrate that Its Paraquat Is Substantially Similar to Syngenta's Before It Can Be Registered in Reliance on Syngenta's Data***

***1. Sinon's Paraquat Likely is Not Substantially Similar to Syngenta's***

Before Sinon may rely fully on Syngenta's data, Sinon must prove that its paraquat is substantially similar to Syngenta's paraquat that is registered in the United States. *See, e.g.,* FIFRA Section 3(c)(7)(A); 40 C.F.R. §§ 152.113(b), 158.30(b)(3), 158.150(b)(iii). Syngenta considers it unlikely that Sinon will be able to prove the substantial similarity of its paraquat to Syngenta's. Syngenta manufactures paraquat for the United States using two high quality processes -- low temperature sodium and ammonium cyanide. Syngenta's processes eliminate impurities and potentially harmful byproducts that result from the manufacture of paraquat with other processes. Syngenta is not currently supplying Sinon with paraquat to support Sinon's application and has no intention to do so.

To Syngenta's knowledge, the only other sources of paraquat in the world are producers outside of the United States. To Syngenta's knowledge, none of these producers employs Syngenta's low temperature sodium or ammonium cyanide manufacturing processes. One of the

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<sup>3</sup> In addition to these concerns, if Sinon filed a statement with EPA certifying that it made an offer-to-pay compensation to Syngenta (*see, e.g.,* EPA Form 8570-34), that also would be a false statement to the government potentially implicating both enforcement and fitness-for-registration issues. *See* Part II.C., below for a further discussion of this issue.

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alternative manufacturing methods that raise particular concerns, for instance, is a high temperature sodium process which produces terpyridine isomers. Terpyridines are extremely toxic in minute quantities. In rat studies, they exhibit acute oral MLDs (median lethal doses) ranging from 8-20 mg/kg, acute dermal MLDs ranging from 0.9-1.8 mg/kg, intraperitoneal MLDs ranging from 0.25-1.0 mg/kg, and acute dermal subcutaneous MLDs ranging from 0.45-0.76 mg/kg. A single drop of the terpyridine isomer 2,2'6',2''-terpyridyl, in a rabbit eye caused death within half an hour, primarily through effects on the central nervous system. This particular manufacturing process also is extremely dangerous because it requires an exothermic reaction that creates a high risk of explosion and thus a significant occupational hazard to plant workers. It has been banned in China since 1999, for instance. Whether Sinon is using this or another process, it is important for EPA to scrutinize the process and the consequent similarity of Sinon's paraquat to Syngenta's.<sup>4</sup>

In addition, EPA should require Sinon to match the safety features that have been required of Syngenta to ensure that any end-use products produced using Sinon's paraquat meet the standards of FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, as amended by the Food Quality Protection Act of 1996 (FQPA), Pub. L. No. 104-170, 110 Stat. 1489. Syngenta has invested, and continues to invest, significantly in product stewardship practices related to paraquat. For instance, EPA's 1987 Registration Standard required the use of an approved emetic in paraquat end-use products. The use of an emetic in paraquat end-use products has been a critical safety feature because it avoids the absorption of paraquat that has been ingested. Many emetics function by irritating the tissues in a person's stomach to induce vomiting, but these types of emetics can increase the rate at which toxic substances are absorbed by human tissues. The emetic used by Syngenta induces vomiting by directly stimulating the human nervous system.

No other company formulates Syngenta's emetic, and the process that must be followed to produce the substance is quite complex. Syngenta is not supplying Sinon with the emetic and has no intention to do so. Sinon must independently assure EPA that any end-use products produced using Sinon's technical will include an emetic with equivalent properties to Syngenta's.

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<sup>4</sup> Syngenta notes that the National Pesticide Information Retrieval Service (NPIRS) is reporting that Sinon has submitted at least one unpublished product chemistry study prepared by several authors, one of which is Syngenta Technology & Projects (*see* MRID 46098802). Syngenta has not authorized Sinon to use Syngenta's product chemistry data in this manner, and is troubled to learn of this action by Sinon for the first time through an NPIRS database. Syngenta is reviewing the potential FIFRA and other implications of Sinon's action and would appreciate EPA's attention to it as well, particularly as Syngenta does not at this time have access to Sinon's data submission to EPA.

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Syngenta obtained a tolerance exemption for its emetic that is contained in EPA regulations. 40 C.F.R. § 180.1065; EPA, *Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; 2-Amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one*, 47 Fed. Reg. 16022 (April 14, 1982). Any emetic that Sinon or its formulators wish to use must also either have a tolerance or an exemption from tolerance under the FFDCA, as amended by the FQPA. In addition, Syngenta was required to submit to EPA product performance data on its emetic, demonstrating the substance is effective as an emetic in paraquat end-use formulations. Sinon or its formulators must be required to supply equivalent data on any emetic that will be used.

Syngenta has employed other notable product stewardship practices. It includes a stenching agent and dye in its paraquat formulations to reduce the likelihood of human ingestion. Some accidental paraquat ingestions that have occurred in the past apparently were attributable to the brown color of paraquat end-use products that caused the product to be mistaken for a cola-type soft drink. Because of the dye that has been added since 1988, Syngenta's paraquat formulations are now colored blue. The dye and stenching agent used together are critical to avoiding accidental ingestion. Pursuant to EPA's 1987 Registration Standard, Syngenta also provides a 24-hour emergency treatment telephone number on its labeling and makes trained personnel available to respond to calls.

To the extent that EPA considers allowing Sinon to obtain a paraquat registration, it is important to ensure that all paraquat registrations are addressed consistently with regard to the foregoing requirements.

**2. *The Results of the Required Analysis Will Determine the Extent to Which Sinon May Rely On Syngenta's Data For Registration***

The precise extent to which Sinon may rely on Syngenta's data will be determined on the basis of the results of the substantial similarity analysis that EPA will conduct after reviewing the product-specific chemistry and product-specific acute toxicity data that Sinon must submit to EPA for this purpose. Sinon also must submit analysis of samples from full-scale production of its paraquat (which, as discussed above, already is occurring). If Sinon has submitted studies based on samples produced on a small scale in a laboratory, these data will not be sufficient to support its registrations because they do not reflect the characteristics of the paraquat product that Sinon expects to be introduced into the marketplace.

There are several potential consequences if Sinon cannot demonstrate the substantial similarity of its paraquat to that of Syngenta's paraquat. These consequences include: (a) Sinon may not be entitled under FIFRA to cite a large portion of Syngenta's paraquat data, potentially including all of Syngenta's toxicology data; (b) Sinon may be required to conduct much of the required testing on its own paraquat; and (c) if the toxicity profile of Sinon's paraquat differs

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from Syngenta's, EPA may conclude that it will not register the Sinon paraquat, or that it will do so only under additional terms and conditions.

Moreover, while EPA must carefully review every application for registration for compliance with applicable standards, the Agency must be particularly vigilant with applications for a registration of a new source of a food use technical grade compound, such as paraquat. Under the standards set forth in FIFRA, the FFDCA, and the FQPA, product safety is driven by the safety of the active ingredient. Each new source of a technical grade product potentially is the basis for numerous end-use registrations. If there are impurities in Sinon's paraquat that are of toxicological concern, additional tolerances may be required.

*C. Sinon's Application is Deficient and May Not be Considered Because Sinon Has Not Provided an Offer to Pay to Syngenta*

*1. FIFRA Section 3(c)(1)(F) and EPA's Implementing Regulations Required Sinon to Provide an Offer to Pay to Syngenta Prior to or At the Same Time Sinon Submitted Its Application to EPA*

A fundamental FIFRA requirement for registration applications is that they be supported by data. FIFRA Section 3(c)(1)(F). Sinon's application should be denied because there is no evidence that it has submitted or intends to submit its own data to meet all of EPA's paraquat data requirements, and yet it has not submitted to EPA an offer to pay data compensation to Syngenta for its reliance on Syngenta's data in support of the application.

FIFRA Section 3(c)(1)(F) provides that EPA may consider data submitted by an original data submitter within the previous 15 years without the original data submitter's permission, "only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer." FIFRA Section 3(c)(1)(F)(iii) (emphasis added). Thus, "[FIFRA] section 3(c)(1)(F) establishes a mandatory licensing scheme": an applicant may cite data originally submitted to EPA by another person only "once [the] applicant has extended a proper offer to pay compensation . . . ." EPA, *Procedures to Ensure Protection of Data Submitters' Rights*, 49 Fed. Reg. 30884, 30889 (Aug. 1, 1984). There would be no basis for an application such as Sinon's were it not for Syngenta's prior data submissions and registration of paraquat.

The protection of an original data submitter's proprietary rights is so fundamental to FIFRA's framework that "if [EPA] determines that an applicant for the registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA section 3(c)(1)(F), the Agency will take steps to deny the application or cancel the registration, as appropriate." 40 C.F.R. § 152.99(c)(3) (emphasis added). Sinon has failed to provide Syngenta an offer to pay prior to citing and requesting EPA's consideration of Syngenta's data, requiring denial of Sinon's application.

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*a. The Fundamental Basis of a FIFRA Application Is Data*

The statute is clear. To begin EPA's review process, any applicant must file a statement that includes the name and address of the applicant; the name of the pesticide; complete labeling and related information; the pesticide's formula; the pesticide's classification; *and a full description of the data on which the application relies*. FIFRA Section 3(c)(1)(A)-(F) (emphasis added). Until the applicant meets all of these requirements, EPA cannot proceed. If the applicant does not submit its own data, it must make an offer to pay and complete EPA's Certification with Respect to Citation of Data (EPA Form 8570-34) to satisfy FIFRA Section 3(c)(1)(F), which in turn calls for offers to have been made to data submitters on whose data the application relies. Without this demonstration, the applicant has not satisfied the very basic requirement that there be health and safety data to support each pesticide application.

There is no question that data are needed for every FIFRA application. In the case of a follow-on application, absent another company's existing database, there would be nothing to "follow onto" and no basis for EPA to begin to evaluate the application. Without the existing database, EPA would not even have the ability to begin a substantial similarity determination; without access to the existing database, there would be nothing against which to judge substantial similarity. Moreover, until an applicant has made a demonstration that it either has its own data or is entitled to rely on another's data and therefore has the basic foundation for an application, EPA's scarce resources should not be devoted to work on the application in place of working on other applications which do contain the basic threshold information.

*b. EPA's Regulations Reinforce That An Applicant Without Its Own Data Package Must Demonstrate Up Front That It Has Complied With FIFRA's Data Citation Requirements*

Consistent with FIFRA's plain language and system of protecting the proprietary rights of original data submitters, EPA's implementing regulations provide that offers to pay to original data submitters must be made either prior to or at the time an application for registration is submitted to EPA, or the application cannot be considered. Under EPA's regulations at 40 C.F.R. § 152.50, an application for registration "must include" certain information, including "materials to demonstrate that [the applicant] has complied with FIFRA Section 3(c)(1)(F)" . . . with respect to satisfaction of data requirements." 40 C.F.R. § 152.50(f); *see also id.* § 152.42 (applications for registration must contain the information specified in § 152.50). Regardless of the citation method that an applicant follows, to comply with FIFRA Section 3(c)(1)(F), the applicant must certify to EPA that it has furnished to an original data submitter *both* a "notification of his intent to apply for registration" and an "offer to pay the person compensation." *See* 40 C.F.R. §§ 152.86(b)(2); 152.93(b)(2); 152.95(b)(2). EPA's rules unambiguously state that "[a]n application is incomplete if any pertinent item specified in § 152.50 has not been submitted . . ." 40 C.F.R. § 152.104. EPA "will not begin or continue the review of an application that is incomplete." *Id.* § 152.105.



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Furthermore, under 40 C.F.R. § 152.80, EPA's regulations reiterate that "to comply (and for the Agency to determine compliance) with the provisions of FIFRA § 3(c)(1)(F)," "an applicant must submit *with his application* for registration" the information required by Subpart E of 40 C.F.R. Part 152 (Procedures to Ensure Protection of Data Submitters' Rights) (emphasis added). Thus, under FIFRA and EPA's rules, unless and until an applicant completes its application by satisfying FIFRA data submission and citation requirements, including furnishing a proper offer to pay to an original data submitter and a certification to EPA that this has been accomplished, EPA lacks a basis to consider, let alone process, the application.

*c. EPA Relies on Data Submitters To Monitor Compliance*

Complete protection of original data submitters' regulatory rights also promotes better EPA decision making, because EPA "rel[ies] heavily on data submitters to monitor compliance with the procedures of . . . subpart [E]." 49 Fed. Reg. at 30899. As discussed below, and as is problematic for a number of reasons, Sinon has not identified to Syngenta whether it is using the cite-all or the selective method or data citation. It is important, particularly with respect to follow-on applicants using the selective or selective cite-all methods, to provide data submitters sufficient opportunity to evaluate the adequacy of an offer to pay. EPA has acknowledged that:

The selective method does not lend itself as readily to monitoring by data submitters, because of the specificity of its procedures and the variety of options available to the applicant to comply with data requirements. A data submitter will not necessarily receive an offer to pay from each applicant, as he would under the cite-all method. Nor will he be able to determine from the Agency's listing of approved applications whether he should have received an offer to pay, since an applicant may have submitted his own study, or cited another data submitter's study.

49 Fed. Reg. at 30900.

Under EPA's regulations, if an applicant chooses to use the selective method, it must (among other things) offer to compensate the data submitter, identifying the "specific requirement involved and . . . the study for which the offer to pay is made (by title, EPA Accession Number or Master Record Identification Number, and date of submission, if possible)." 40 C.F.R. § 152.93(b)(2)(ii).<sup>5</sup> By EPA requiring a *timely* offer to pay that

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<sup>5</sup> EPA also encourages follow-on applicants to provide copies of their data matrices and proposed labels to data submitters with their compensation offers. See Draft PR Notice 2002-XXXX, at 3-4.

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incorporates these features, a data submitter will better be able to determine the particular data on which the follow-on applicant is relying and inform EPA whether sufficient data have been cited.

From a practical standpoint, it is important for EPA to know, at the outset of the application process, on what data the application is being supported. This information is required for EPA to begin evaluating the proposed composition and labeling of the product, and questions may arise during the application process related to the specific information supplied with the application (for instance, requiring changes to the proposed label). Follow-on applicants make it unnecessarily difficult for EPA and original data submitters to assess applications when they are not provided readily available information.

Moreover, if the follow-on in fact identifies a method of data reliance to EPA with its application, as it should, it is not entitled to do so without first having made an offer-to-pay compensation. An applicant simply does not have the right to rely on another company's data until it makes a compensation offer. FIFRA Section 3(c)(1)(F)(iii).

*d. 40 C.F.R. § 152.84 Is Not an Open Invitation To Manipulate the Statutory Data Citation System*

Follow-on applicants at times have erroneously contended that they may comply with FIFRA Section 3(c)(1)(F) by making an offer to pay at any time prior to EPA's approval of an application, citing 40 C.F.R. § 152.84. Section 152.84 provides that "All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA's approval of the application. The Agency will not approve any application until it determines that all required materials have been submitted and are acceptable." The follow-on applicants' assertion above, does not square with the plain language of FIFRA Section 3(c)(1)(F)(iii), FIFRA's system for protecting data rights, and the foregoing framework of regulations under 40 C.F.R. Part 152.

There are many activities that an applicant must undertake to obtain approval of a registration application, including satisfying numerous data requirements. Some of these evolve in discussion with EPA during the review process, particularly for the original registrant which is generating the database for the first time. Thus, it is sensible that there be some provision for supplementing applications given the dynamic nature of the EPA review process.

With regard to data citation and offers-to-pay, however, an applicant knows up front whether it will be relying in whole or in part on another company's data. There can be no excuse for delaying this compliance with the express terms of the statute and EPA's regulations, cited above. The applicant must do what it can up front to satisfy the basic statutory and regulatory requirements. While it is predictable that corrections and additions may need to be made as a function of the dynamic application review process, this is not an excuse for ignoring or delaying inevitable portions of the application at the initiation of the application process. Section 152.84



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is not applicable to the requirement to designate at the outset of the application process the data on which the applicant is relying. Even if an offer must at some point be amended (which § 152.84 would allow) because EPA requires more data under the selective method, for example, it would violate FIFRA and EPA's regulatory system to countenance the refusal of an applicant to make a proper data citation offer under one of the available citation methods at the outset of the application process.

EPA must construe 40 C.F.R. § 152.84 consistent with this provision's fundamental purpose of ensuring that EPA considers all information necessary for determining an application's compliance with FIFRA prior to approving the application. Section 152.84 is titled "When materials must be submitted to the Agency." With respect to a specific offer to pay, the only information that EPA need consider in most cases is whether the offer to pay has been given. *See* 49 Fed. Reg. at 30898 ("Applications under the cite-all method will be examined primarily to determine that the applicant's *certification* and *general* offer to pay have been correctly submitted. (*The Agency will not ascertain the data submitters to whom the applicant had written.*)" Applications under the selective method will be reviewed to ensure "that . . . [the] *certification* reflects that required offers to pay . . . *have been made* . . .") (emphases added). Because specific offers to pay are required to be given solely for the benefit and protection of original data submitters' rights, as a matter of practice they are not submitted to EPA to demonstrate compliance with FIFRA's requirements. *See id.* Although this practice is inconsistent with the plain language of FIFRA Section 3(c)(1)(F)(iii) ("only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter....") and should be corrected by EPA, it generally may be tolerated for purposes of protecting data submitters' rights if EPA is informed by way of a certification, using EPA Form 8570-34 (Certification with Respect to Citation of Data)<sup>6</sup>, that specific offers to pay were provided to original data submitters before or contemporaneously with the submission of the application to EPA. Certainly, 40 C.F.R. § 152.84 cannot countermand the more specific statutory and regulatory provisions that only allow reliance on data (which is the heart of the application) after an offer to pay is made.

EPA's rationale for allowing the review of follow-on applications while awaiting limited information, set forth in the Preamble to the 1984 Final Rule, is consistent with the statutory mandate of prompt offers to pay:

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<sup>6</sup> If Sinón has filed such a statement with EPA certifying that it made a compensation offer, that would have been a false statement to the government implicating both enforcement and fitness-for-registration issues.

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[T]he correspondence requirements of this subpart may take some time, and . . . an applicant may not wish to await *responses* in all cases before filing his application . . . .

49 Fed. Reg. at 30897 (emphasis added). The example given by EPA in the Preamble is that under the selective method, when an applicant wishes to claim a data gap, it must notify data submitters, who then have 60 days to indicate whether they have submitted pertinent data and thereby demonstrate that a gap does not exist and may not be claimed by the follow-on applicant. EPA explains in the Preamble that applicants need not await the expiration of the 60-day period before applying for registration and that EPA's review can proceed concurrently with the 60-day data gaps period. *Id.*

First, it is a far cry from this example to concluding that compensation offers can be delayed to a time of the data citer's choosing after the application is filed and EPA begins to expend resources reviewing the application. EPA's concern of not delaying applications bears no relation to the timing of an applicant's tendering of a specific offer to pay, because an applicant does not require receipt of any information from an original data submitter prior to making such an offer.

Second, EPA's specific allowance of later submissions to the Agency of "certification statements," but not specific offers to pay, manifests EPA's understanding that an applicant must tender a specific offer to pay to an original data submitter prior to or at the time of submitting its application to EPA. *See* 49 Fed. Reg. at 30893-94 ("[T]he applicant will be permitted to submit his *certification and general offer to pay* at any time before registration is approved. The Agency will not delay the review of the application pending receipt of *these statements . . . .*") (emphases added); *see id.* at 30896 ("The applicant must write to each person on the Data Submitters List and make an appropriate [specific] offer to pay . . . . *He then submits* to the Agency, either at the time of application or before its approval, his *general offer to pay and certification statement.*") (emphases added).<sup>7</sup> Insofar as an applicant reads this as permission to delay making compensation offers until the eve of registration, it is a misreading of the statute and the express terms of EPA's regulations, and can serve no purpose other than an illegitimate one of seeking to hide the registration process from the very entity whose data the process relies upon.

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<sup>7</sup> EPA stated that it planned to clarify through guidance when an applicant must provide to an original data submitter an offer to pay versus when the applicant must provide documentation to EPA that the offer to pay has been made. *See* EPA, *Draft Guidance on How to Comply With Data Citation Regulations*, 67 Fed. Reg. 68866, 68868 (Nov. 13, 2002).

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Furthermore, EPA issued for public comment in 2002 a draft Pesticide Registration Notice that is intended to "clarif[y] and emphasize[] the existing obligations of applicants . . . who choose to cite other companies' data to satisfy EPA data requirements." Draft PR Notice 2002-XXXX, *Compliance with Data Citation Regulations*, at 1. While the draft PR Notice does not specifically address when an applicant must furnish an offer to pay or when the applicant must provide a certification to EPA, it states that an applicant's specific offer to pay "must include" "[n]otice of his intent to apply for registration." Draft PR Notice 2002-XXXX, at 3. Because a notice of *intent to apply* plainly must be issued prior to or contemporaneous with the application itself, so too, it logically follows, must the offer to pay.

2. ***Sound Policy, Practicality and Equity Dictate That Offers to Pay Must be Provided Prior to or At the Time a Registration Application is Submitted to EPA***

In addition to the plain meaning of FIFRA Section 3(c)(1)(F) and its implementing regulations, all parties benefit from prompt offers to pay. EPA's scarce resources should not be used to process applications unless and until the applicant has done its part to complete fundamental elements of its application that are within its control. If the applicant has not offered to pay compensation, it is not entitled to rely on another company's data, there is no data underlying the application, nor may EPA consider the application complete for review. In its draft PR Notice, EPA observed that "[i]ncomplete and otherwise inadequate offers of compensation are a drain on the Agency, data submitter, and applicant resources" because they "can increase the potential for adversarial petitions brought under 40 C.F.R. § 152.99." Draft PR Notice 2002-XXXX, at 1, 7. Conversely, the number of petitions filed may be expected to decline if the follow-on applicants were to follow FIFRA's plain requirements and place original data submitters in a position to negotiate data completeness and compensation issues at the outset of the application process.

Consistent with these principles, offers to pay should be provided to original data submitters at the outset of the application process. To do otherwise, undermines the protection of data rights in at least three additional fundamental ways. First, it opens up to potential argument the trigger date for the 15-year compensability period. In actuality, the period begins on the date of the follow-on's application, as the follow-on applicant would have no basis for its application absent the data owner's prior submission of data. Nonetheless, it is predictable that follow-on applicants will try to argue that the 15-year compensability period is not triggered until the offer to pay is made and thereby seek to diminish their data compensation obligations unfairly by trying to eliminate compensation for data that would fall off the 15-year list during the time between the original application and the date of the compensation offer.

Second, manipulation of the offer date until late in the registration process, even up to the date of registration in some instances, seriously undermines the data owner's rights and opportunity to petition to deny applications that do not meet FIFRA requirements at a

Patricia A. Roberts  
January 23, 2004  
Page 18

meaningful time and in a meaningful manner. Typically the offer to pay is the first information provided to an original data submitter about the extent of the follow-on's reliance on its data, if not the first notice that another entity is relying on the data in the first place. Delay in issuing the offer to pay abridges data submitters' rights by facilitating a potentially long period during which the applicant is communicating with EPA about its application, but during which the data owner has not been properly advised of data reliance and provided an opportunity to petition EPA at a meaningful time and in a meaningful way.

One of the specific bases enumerated in EPA's rules for bringing a petition to deny is an applicant's failure to make an appropriate offer to pay. 40 C.F.R. § 152.99(a)(2)(vi). It is difficult to impossible for the data owner to file an efficient and meaningful petition when the basic facts about another company's reliance on its own data are being withheld from it. Moreover, it is inconsistent with the protections in FIFRA Section 3 to allow unrelated companies to use a data submitter's data and facilitate a period between EPA's granting of a registration and EPA's subsequent canceling of the registration based on deficiencies in the application that a data submitter was not provided an opportunity earlier to identify during which the follow-on applicant is accorded free use of the data submitter's data.

It is predictable that follow-on applicants would seek to obscure from the data owner the details of their reliance on data to prevent data owners from filing petitions -- expressly provided for by law -- pointing out the deficiencies in the applications. For the petition process to be meaningful, data owners must at least have timely notice of the information required in compensation offers.

Third, delay of the offer date unfairly delays the data owner's opportunity to initiate arbitration if compensation cannot be negotiated. FIFRA Section 3(c)(1)(F)(iii) contains a 90-day period, triggered by delivery of a compensation offer, during which discussions over compensation may occur. No party may initiate arbitration until after that 90-day period. The arbitration process, when needed, is lengthy enough on its own, and it is unfair to delay it further, particularly when in actuality the follow-on already is obtaining the benefits of the data owner's data at EPA.

In each of these three instances, delay of offers is inconsistent with the fundamental fact that the follow-on would have no basis to apply for registration in the first place were it not for the data submitter's existing data. As a matter of equity, an applicant should not benefit from an unrelated company's data without notifying the data submitter that the data are being used to support the applicant's application and offering to pay compensation. Original data submitters incur substantial costs and risks in generating studies prior to submitting a registration application. Follow-on applicants, at a minimum, should be expected to make an offer to pay for their reliance on those studies at the outset of the application process to afford data submitters a sufficient opportunity to negotiate a fair price or initiate arbitration in a timely fashion.

Patricia A. Roberts  
January 23, 2004  
Page 19

### III. CONCLUSION

Sinon's application to register Paraquat Technical Concentrate is fundamentally flawed and must be denied:

- if Sinon aided in the importation of unregistered pesticide for domestic use or furthered a fraud on U.S. and foreign officials with respect to Marman's purported use of existing stocks of Zeneca paraquat, which if established would demonstrate that Sinon is unfit to hold the sought after registration;
- if Sinon cannot demonstrate that its paraquat is substantially similar to Syngenta's; or
- because Sinon has failed to provide an offer to pay compensation for reliance on Syngenta's data pursuant to FIFRA Section 3(c)(1)(F).

Syngenta respectfully requests that EPA deny Sinon's pending application for registration of Paraquat Technical Concentrate, or at a minimum discontinue processing the application until EPA determines Sinon's fitness to receive a registration, Sinon demonstrates that its paraquat is substantially similar to Syngenta's, and Sinon makes a legally sufficient compensation offer.

Syngenta requests that EPA confirm that it will not grant Sinon's applications for registration before making a final determination on this Petition. *See* 40 C.F.R. § 152.99(c)(3). Syngenta further requests that because EPA's action on this Petition is final agency action subject to judicial review, the Agency grant Syngenta ten days in which to seek an administrative or judicial stay prior to any final approval of the registration that EPA may decide to grant.

BEVERIDGE & DIAMOND, P. C.

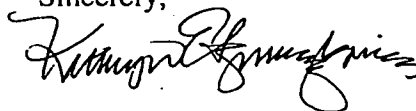
Patricia A. Roberts  
January 23, 2004  
Page 20

**IV. NO WAIVER**

In filing this Petition, Syngenta does not waive any of the rights available to it in any forum to seek further relief under FIFRA or any other source of law.

Thank you for your consideration.

Sincerely,



Kathryn E. Szmuszkovicz

Enclosures

cc: J. Jones (EPA)  
L. Rossi (EPA)  
D. Stubbs (EPA)  
J. Tompkins (EPA)  
Y. Hopkins (EPA)  
A. Pontius (EPA)  
C. Eichenwald (EPA)  
B. Dyer (EPA)  
E. Brown (ChemReg, Agent for Sinon)  
R. Renes (Marman)



Patricia A. Roberts  
January 23, 2004  
Page 21

CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of January, 2004, copies of the attached *Petition To Deny Sinon Corporation's Application to Register Paraquat Technical Concentrate* were delivered to the following by the method specified below:

Patricia Roberts  
Associate General Counsel for  
Pesticides and Toxic Substances  
Office of the General Counsel  
U.S. Environmental Protection Agency  
Ariel Rios Building, Mail Code 2333A  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460

Hand Delivery

Elizabeth Anne Brown  
Registration Agent for Sinon Corporation  
ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

FedEx and Certified Mail

  
Katherine A. Shortell



# ChemReg<sup>®</sup>

INTERNATIONAL, LLC

Rec'd  
10-16-03

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

October 14, 2003

By Certified Mail, Return Receipt No: 7099 3400 0011 2343 1863

SYNGENTA CROP PROTECTION, INC.  
ZENECA AG PRODUCTS, INC.  
BOX 18300  
GREENSBORO NC 27419

Re: Intent to Apply for a Registration Containing the Active Ingredient Paraquat Dichloride

To whom it may concern:

Pursuant to Subpart E of Part 152 of Title 40 of the Code of Federal Regulations, this letter is your notice that Sinon Corporation intends to apply to the U.S. Environmental Protection Agency to register the pesticide product Paraquat Technical Concentrate containing the active ingredient paraquat dichloride, and intends to cite data submitted by you in support of our application.

At the appropriate time, Sinon Corporation will make an offer to pay compensation as required by the Federal Insecticide, Fungicide, and Rodenticide Act.

Sincerely,



Elizabeth Anne Brown  
Registration Agent for Sinon Corporation

cc: Sinon Corporation

---

**CONSULTANTS TO SUCCESS<sup>®</sup>**

Expertise in Toxicology, Residue and Product Chemistry, Environmental Fate, Efficacy, Registration Strategies and Implementation, Regulatory Compliance, Label Development, Exposure and Risk Assessments, Data Citation and Compensation, Study Design and Monitoring.





# RegWest Company

P.O. Box 2220 Greeley, CO 80632-2220 970/353-0611 FAX 970/353-0613

Certified Mail RRR  
Z 193 643 548

October 30, 1998

Document Processing Desk  
Office of Pesticide Programs - 7505C  
U.S. ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
Washington, DC 20460-0001

ATTN: Jim Tompkins, Product Manager 25

Dear Mr. Tompkins:

SUBJECT: Marman USA, Inc.  
Marman Herbiquat® Herbicide  
EPA Reg. No. 48273-27  
Agency Letter dated October 19, 1998 (copy attached)

On behalf of its client *Marman USA, Inc.*, RegWest Company is responding to the EPA letter of October 19, 1998. RegWest Company will act as sole agent in this endeavor.

According to current EPA policy, Marman USA's registrations (EPA Reg. Nos. 48273-6 and 48273-27) are not immediately affected by the cancellation of EPA Reg. No. 10182-115 due to Marman's possession of existing stocks which were purchased well in advance of September 26, 1998.

It is our understanding EPA policy allowed Zeneca legal distribution of its existing stocks of EPA Reg. No. 10182-115 up to September 26, 1998 and that this existing stocks date does not apply to material released for shipment or distributed prior to September 26, 1998, such as the stocks of EPA Reg. No. 10182-115 currently warehoused at Marman USA.

PR Notice 97-7 provides the most succinct explanation of this EPA policy:

The existing stocks provision will normally be based on the released for shipment date. A product is packaged, labeled and released for shipment by a producing establishment when the product has been produced, packaged and labeled, and it is the intent of the producer to introduce such product in commerce. The phrase packaged, labeled and released for shipment is only relevant at the producing establishment level.

In June 1991 the EPA published a Federal Register notice to be used as a guide for Agency decision-making regarding the sale, distribution and use of existing stocks of pesticide products whose registrations under the FIFRA are amended, canceled or suspended. This policy was amended in a Federal Register notice in April 1996. Both Federal Register Notices support the unlimited distribution of canceled pesticide products which have already been distributed prior to the released for shipment date unless there are significant risk concerns associated with the cancellation of the pesticide product. To our knowledge, no significant risk concerns were or are associated with the cancellation of EPA Reg. No. 10182-115.


Based on the EPA's existing stocks policy, Marman USA will hold legal and viable registrations for EPA Reg. Nos. 42873-6 and 48273-27 until Marman has depleted its stocks of EPA Reg. No. 10182-115 and/or appropriate documents are filed with and accepted by the EPA providing a new source of active ingredient.

In the future we would appreciate the EPA providing a more reasonable time frame in which to respond to its letters and/or requests, such as 30 days from receipt of a letter instead of 15 days from the date of the letter.

Please contact me at (970) 353-0611 if you require additional information or have any questions concerning this submission.

Regards,

REGWEST COMPANY



Kim Davis, CC, APC

Attachment

pc: MUI-Renes. R.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**COPY**

OCT 19 1998

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

RECEIVED OCT 27 1998

Ms Kim Davis  
REGWEST COMPANY  
P. O. Box 2220  
Greeley, CO 80632-2220

Dear Ms. Davis:

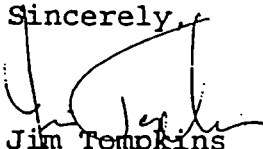
SUBJECT: Amendment  
Marman Herbiquat Herbicide  
EPA Registration No. 48273-27  
Your Application Dated August 13, 1998

The amendment referred to above, submitted in accordance with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is not acceptable due to the following:

1. Your 100% repack of EPA 48273-6 was rejected in a letter from the EPA to you, dated September 25, 1998 because the product EPA Reg. No. 10182-115 had been voluntary canceled, effected June 6, 1998.
2. The expiration date for the use of existing stock was September 26, 1998.

Since Zeneca has canceled EPA Reg. No. 10182-115, and you can no longer repackage this product, you will have to submit a new CSF. Please reply within 15 days of the date of this letter.

Sincerely,

  
Jim Tompkins  
Product Manager (25)  
Herbicide Branch  
Registration Division (7505C)

Enclosure

72

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Exhibit 3



Certified Mail RRR

7001 0320 0004 1519 3730



March 22, 2002

Jim Tompkins, Product Manager 25  
Document Processing Desk  
Office of Pesticide Programs – 7504C  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001

Dear Mr. Tompkins:

**Subject:** Marman USA, Inc.  
Marman Herbiquat® Herbicide  
EPA Reg. No. 48273-27  
Your Letter Dated August 28, 2000

On behalf of its client **Marman USA, Inc.**, RegWest Company is responding to your letter of August 28, 2000. RegWest Company will act as sole agent in this endeavor.


The August 28, 2000 letter states:

*With this letter we are hereby withdrawing the condition contained in our March 27, 2000 letter approving Marman's registration of EPA Reg. No. 48273-27. In lieu of that, EPA accepts Marman's offer to provide, in writing, a letter to the EPA Product Manager for paraquat, on or about March 27, 2002, advising whether Marman possesses existing stocks of its active ingredient source (EPA Reg. No. 10182-115) and, if so, whether it is still relying upon its currently approved Confidential Statement of Formula.*

This letter serves as the advisory that Marman does indeed possess existing stocks of its active ingredient source, EPA Reg. No. 10182-115, and are still relying upon its currently approved Confidential Statement of Formula dated October 19, 1998.

Please contact me at (970) 353-0611 if you require additional information.

Regards,  
RegWest Company

  
Kim Davis, CG, APC  
Consultant/Agent

pc: MUI – Renes, R.

30856 Rocky Road  
Greeley, CO 80631-9375  
970-353-0611  
970-353-0613 Fax  
regwest@aol.com

(37)

3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 28 2000

Ms. Kim Davis  
Consultant/Agent for  
MARMAN USA INC.  
P. O. Box 2220  
Greeley, CO 80632-2220

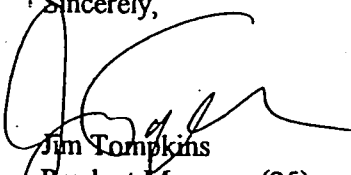
Dear Ms. Davis:

SUBJECT: Marman Paraquat Concentrate  
EPA Registration No. 48273-27  
Your Letter Dated June 22, 2000

This is in response to your letter of June 22, 2000 which was submitted in response to EPA's approval of an amendment to Marman's Herbiquat Herbicide registration EPA Reg. No. 48273-27 and imposition of the condition that Marman submit a "correct" CSF two years from the date of approval of the amendment.

With this letter we are hereby withdrawing the condition contained in our March 27, 2000 letter approving Marman's registration of EPA Reg. No. 48273-27. In lieu of that, EPA accepts Marman's offer to provide, in writing, a letter to the EPA Product Manager for Paraquat, on or about March 27, 2002, advising whether Marman possesses existing stocks of its active ingredient source (EPA Reg. No. 10182-115) and, if so, whether it is still relying upon its currently approved Confidential Statement of Formula (CSF). If you have any questions, please contact me at (703) 305-5697.

Sincerely,



Jim Tompkins  
Product Manager (25)  
Herbicide Branch  
Registration Division (7505C)

CONCURRENCES

|         |              |  |  |  |  |  |  |    |
|---------|--------------|--|--|--|--|--|--|----|
| SYMBOL  | 7505C        |  |  |  |  |  |  |    |
| SURNAME | MINOR, E.    |  |  |  |  |  |  |    |
| DATE    | Aug 28, 2000 |  |  |  |  |  |  | 23 |

(38)



PIPER  
MARBURY  
RUDNICK  
& WOLFE LLP

*Stubbs*

1200 Nineteenth Street, N.W.  
Washington, D.C. 20036-2412  
www.piperrudnick.com

PHONE (202) 861-3900  
FAX (202) 223-2085

WRITER'S INFORMATION

michael.novak@piperrudnick.com  
PHONE (202) 861-3886

June 22, 2000

*6/26/00*

*295*

Mr. Jim Jones  
Registration Division Director, OPP  
United States Environmental Protection Agency  
Office of Pesticide Programs (7505C)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Re: CSF Condition on Marman Herbiquat Herbicide, # 48273-27

Dear Jim:

This follows up our recent conversation regarding EPA's March 27, 2000 approval of an amendment to Marman's Herbiquat herbicide registration (EPA Reg. No. 48273-27), and EPA's imposition of the condition that Marman submit a "correct" Confidential Statement of Formula (CSF) two years from the date of approval of the amendment.

While it remains Marman's position that this condition is unwarranted and inappropriate, Marman very much wishes to reach a mutually acceptable resolution of this matter with the Agency. As I explained in our phone conversation, we are concerned that the condition could be construed by the Agency as prohibiting Marman from marketing its product if there is a delay in its approval. Therefore, in lieu of this condition, Marman would propose to commit to advise EPA, in writing, on or about March 27, 2002, whether Marman still possesses existing stocks of its active ingredient source and, if so, whether it is relying upon its currently approved CSF.

*24*


Mr. Jim Jones  
June 22, 2000  
Page 2

Thus, we respectfully propose that EPA issue a letter to Marman stating the following:

By this letter we are hereby withdrawing the condition contained in our March 27, 2000 letter approving Marman's registration (EPA Reg. No. 48273-27). In lieu of that, EPA accepts Marman's offer to provide, in writing, a letter to the EPA Product Manager for Paraquat, on or about March 27, 2002, advising whether Marman possesses existing stocks of its active ingredient source (EPA Reg. No. 10182-115) and, if so, whether it is still relying upon its currently approved Confidential Statement of Formula (CSF).

We believe this approach addresses EPA's concerns while protecting the reasonable property interests of Marman in its registration. Please give me a call if you would like to discuss our proposal further.

Sincerely,



Michael T. Novak

/mtn

cc: Jim Rathvon, Piper Marbury Rudnick & Wolfe LLP  
Kim Davis, RegWest Company

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 27 2000

Ms. Kim Davis  
Consultant/Agent for  
MARMAN USA INC.  
P. O. Box 2220  
Greeley, CO 80632-220

Dear Ms. Davis:

SUBJECT: Marman Paraquat Concentrate  
EPA Registration No. 48273-27  
Your Letter Dated March 13, 2000

In response to your letter of March 13, 2000 which was submitted in accordance with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable.

The registration for the above product is conditioned upon submission of a correct CSF for 48273-27 two (2) years from the date of this letter. If you have any questions, please contact me at (703) 305-5697.

Sincerely,

Jim Tompkins  
Product Manager (25)  
Herbicide Branch  
Registration Division (7505C)

CONCURRENCES

|           |              |  |  |  |  |  |  |  |
|-----------|--------------|--|--|--|--|--|--|--|
| SYMBOL ▶  | 7505C        |  |  |  |  |  |  |  |
| SURNAME ▶ | MINOR, E.    |  |  |  |  |  |  |  |
| DATE ▶    | Mar 27, 2000 |  |  |  |  |  |  |  |



# RegWest Company

P.O. Box 2220 Greeley, CO 80632-2220 970/353-0611 FAX 970/353-0613

FedEx  
AB 8157 7198 4953

March 13, 2000

Mr. Don Stubbs, Chief, Herbicides Branch  
Office of Pesticide Programs  
Document Processing Desk - 7505C  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Dear Mr. Stubbs:

SUBJECT: Marman USA, Inc.  
Marman Herbiquat Herbicide, EPA Reg. No. 48273-27

On behalf of its client *Marman USA, Inc.*, RegWest Company is submitting the attached *Commercial Invoice* in response to your request. RegWest Company will act as sole agent in this endeavor.

This Commercial Invoice was previously submitted to the Agency in response to Mr. Tompkins' May 25, 1999 letter. However, it has come to our attention, through conversations reported by Mr. Mike Novak, that the Agency took exception to the quantity information being sanitized from the previously submitted Invoice. The quantity information has not been sanitized from this invoice, but we continue to sanitize the nonessential pricing information ("Unit Price," "Amount in USD" and "Total Value"). We request the quantity information be treated as CBI.


We also advise the Agency this is a single invoice and is not necessarily representative of the number of invoices or amount of inventory and is provided purely for information purposes per the James Jones Internal Memo dated November 21, 1997.

We understand from Mr. Novak that upon receipt of this information a letter will immediately be prepared and mailed stating:

1. The Agency conditionally approves the October 19, 1998 Confidential Statement of Formula for this product; and
2. That no time restraints concerning the manufacture and distribution of subject product will be a part of the conditions of approval.

Please contact me at (970) 353-0611 if you require additional information.

Regards,  
RegWest Company

  
Kim Davis, CC, APC  
Consultant/Agent  
Attachment  
pc: MUI - Renes, R.

27



**MARMAN PARAQUAT IMPORTS INTO THE UNITED STATES**  
**November 2001 - July 2003**

| <b>Manufacturer</b> | <b>Shipment Arrival Date</b> | <b>Gross Shipment Weight (Tech. lbs.)</b> | <b>Port of Entry or Customs District</b> | <b>U.S. Formulator/Marketer</b> |
|---------------------|------------------------------|-------------------------------------------|------------------------------------------|---------------------------------|
| Sinon (Taiwan)      | 17-Jul-03                    | 40,905                                    | Pt. Everglades, FL                       | Marman                          |
| Sinon (Taiwan)      | 24-Jun-03                    | 40,906                                    | Savannah, GA                             | Reexported (Marman)             |
| Sinon (Taiwan)      | 20-Jun-03                    | 8,181                                     | Savannah, GA                             | Marman                          |
| Sinon (Taiwan)      | 20-Jun-03                    | 13,409                                    | Savannah, GA                             | Marman                          |
| Sinon (Taiwan)      | 03-May-03                    | 81,812                                    | Savannah, GA                             | Reexported                      |
| Camfall (Taiwan)    | 09-Jan-03                    | 8,183                                     | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 28-Dec-02                    | 40,917                                    | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 09-Sep-02                    | 40,917                                    | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 03-Sep-02                    | 40,917                                    | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 07-Aug-02                    | 40,917                                    | Savannah, GA                             | Marman                          |
| Marman (Jamaica)    | 19-Jul-02                    | 40,917                                    | Pt. Everglades, FL                       | Reexported                      |
| Camfall (Taiwan)    | 29-May-02                    | 40,917                                    | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 22-May-02                    | 81,834                                    | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 12-May-02                    | 81,834                                    | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 16-Apr-02                    | 81,834                                    | Savannah, GA                             | Marman                          |
| Camfall (Taiwan)    | 06-Apr-02                    | 81,834                                    | Charleston, SC                           | Marman                          |
| Camfall (Taiwan)    | 31-Mar-02                    | 40,917                                    | Charleston, SC                           | Marman                          |
| Camfall (Taiwan)    | 14-Mar-02                    | 40,917                                    | Savannah, GA                             | Unknown                         |
| Camfall (Taiwan)    | 09-Mar-02                    | 40,917                                    | Charleston, SC                           | Marman                          |
| Camfall (Taiwan)    | 26-Jan-02                    | 40,917                                    | Charleston, SC                           | Reexported                      |
| Camfall (Taiwan)    | 09-Nov-01                    | 40,388                                    | Savannah, GA                             | Reexported (Marman)             |

Source: Port Import/Export Reporting Service (PIERS), Journal of Commerce



Exhibit 5

**MARMAN PARAQUAT EXPORTS FROM THE UNITED STATES  
TO CARIBBEAN PORTS**

**January - December 2002**

---

| <b>Country</b> | <b>Shipment Date</b> | <b>U.S. Port</b>   | <b>Technical Weight<br/>(Pounds)</b> |
|----------------|----------------------|--------------------|--------------------------------------|
| Barbados       | 01/18/02             | Miami, FL          | 42,400                               |
| Cayman Isl.    | 08/03/02             | Tampa, FL          | 1,640                                |
| Trinidad       | 01/24/02             | Pt. Everglades, FL | 42,400                               |

Source: Port Import/Export Reporting Service (PIERS), Journal of Commerce





**MARMAN USA, Inc.**

TELEPHONE: (813) 286-2503

FAX: (813) 287-1348

e-mail: [info@marmanusa.com](mailto:info@marmanusa.com)

Web Site: <http://www.Marmanusa.com>

**MAILING ADDRESS:**

P.O. BOX 22829, TAMPA, FLORIDA 33622-2829

500 N. WESTSHORE BLVD., SUITE 405, TAMPA, FLORIDA 33609

July 19, 2001

Document Processing Desk (CERT)  
Office of Pesticide Program  
US Environmental Protection Agency  
401 M. Street S.W.  
Washington D.C. 20460

Dear Document Processing Agent:

By this letter we are requesting two (5) original Certificates of Product Registration (with the Gold EPA Seal) for the following product:

MARMAN HERBIQUAT HERBICIDE

EPA Reg. No. 48273-27

JT

We thank you in advance for your assistance.

Sincerely yours,

Marman USA Inc.

Robert T. Renes, Vice President



10



**MARMAN USA, INC.**

TELEPHONE: (813) 286-2503

FAX: (813) 287-1348

e-mail: [info@marmanusa.com](mailto:info@marmanusa.com)

Web Site: <http://www.Marmanusa.com>

**MAILING ADDRESS:**

P.O. BOX 22829, TAMPA, FLORIDA 33622-2829

500 N. WESTSHORE BLVD., SUITE 405, TAMPA, FLORIDA 33609

November 27, 2001

Document Processing Desk (CERT)  
Office of Pesticide Program  
US Environmental Protection Agency  
401 M. Street S.W.  
Washington D.C. 20460

Dear Document Processing Agent:

By this letter we are requesting two (3) original Certificates of Product Registration (with the Gold EPA Seal) for the following product:

/ MARMAN HERBIQUAT HERBICIDE / Jim EPA Reg. No. 48273-27

We thank you in advance for your assistance.

Sincerely yours,

Marmman USA Inc.  
Robert T. Renes, Vice President

2001 11/27

11/27/01 10:10 AM

11/27/01 10:10 AM

11/27/01 10:10 AM

11/27/01 10:10 AM

11/27/01 10:10 AM

11/27/01 10:10 AM



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

SEP 18 2001

I, Jim Tompkins, Product Manager of Team Number 25, Herbicide Branch, Registration Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), confirm that the pesticide product listed below is of the date of this letter, registered with EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that accordingly, the product may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of the product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with laws of the United States of America or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify any recipient of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued a registration number for the product listed below:

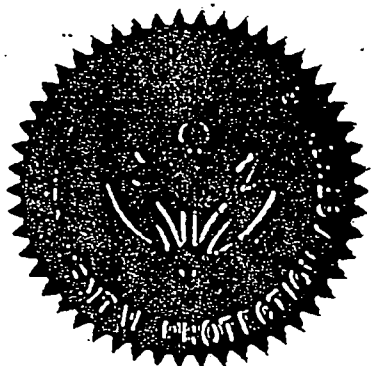
MARMAN USA, INC.  
500 N. Westshore Blvd, Suite 405  
Tampa, Florida 33609

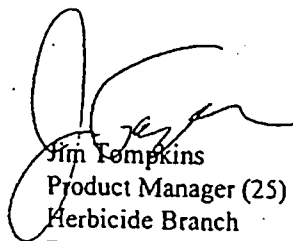
EPAREG.No.

Name of Product

48273-27

Marman Herbiquat Herbicide



  
Jim Tompkins  
Product Manager (25)  
Herbicide Branch  
Registration Division (7505C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

JAN 24 2002

I, Jim Tompkins, Product Manager of Team Number 25, Herbicide Branch, Registration Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), confirm that the pesticide product listed below is of the date of this letter, registered with EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that accordingly, the product may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

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EPA has issued a registration number for the product listed below to:

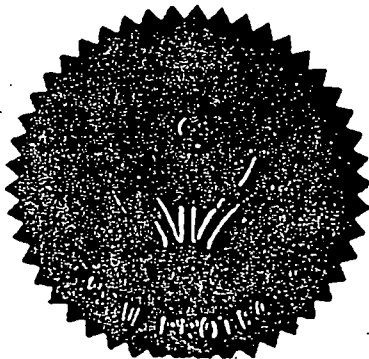
Marman USA, Inc..  
500 N. Westshore Blvd., Suite 405  
Tampa, Florida 33609

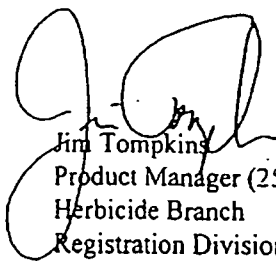
EPA Reg.No.

Name of Product

48273-27

MARMAN HERBIQUAT HERBICIDE



  
Jim Tompkins  
Product Manager (25),  
Herbicide Branch  
Registration Division (7505C)

4

Exhibit 7



> -----Original Message-----

> From: [Buckingham.Carol@epamail.epa.gov](mailto:Buckingham.Carol@epamail.epa.gov)

> [mailto:[Buckingham.Carol@epamail.epa.gov](mailto:Buckingham.Carol@epamail.epa.gov)]

> Sent: Wednesday, January 15, 2003 9:12 AM

> To: Waynick Sharon USGR

> Subject: 48273 - Marman is inactive and so is the establishment - see  
> below

>

>

>

> As you can see both company and establishment are inactive:

>

> PGM: SS2112N1 U. S. ENVIRONMENTAL PROTECTION AGENCY

> 01/14/03

> MAP: SS2112M1 : SECTION SEVEN TRACKING SYSTEM

> 14:02:21

> COMPANY DETAIL

>

>

---

> Company Number: 048273 Status: INACTIVE DUNS Number: .

>

> Reason: NO LONGER PRODUCING (PREV.

> UNKNOWN)

> Company Name : MARMAN (USA) INC.

>

> Site Address : 5401 W. KENNEDY BLVD.

> City : TAMPA State: FL ZIP Code: 33609

>

> County : HILLSBOROUGH

> Mail Address : 5401 W. KENNEDY BLVD.

> City : TAMPA State: FL ZIP Code: 33609

>

> State Incorp.: FL Officer : RENES, ROBERT

> Date Incorp.: 04/21/1981 Title : VP

> Active Estab : 0 Telephone : 813-286-2503

> Inactive Estab: 1 Date Signed: 04/29/1991

> Type of Ownership: CORPORATION

>

>  
>  
> PGM: SS2122N1 U. S. ENVIRONMENTAL PROTECTION AGENCY  
> 01/14/03  
> MAP: SS2122M1 SECTION SEVEN TRACKING SYSTEM  
> 14:03:58

> ESTABLISHMENT DETAIL  
>

---

> Estab. Number: 048273-FL -001 Status: INACTIVE DUNS Number: -

> -

Reason: NO LONGER PRODUCING (PREV.

> UNKNOWN)

> Estab. Name : MARMAN (USA) INC.

> Site Address : 5401 W. KENNEDY BLVD.

> City : TAMPA State: FL ZIP Code: 33609

> -

> County : HILLSBOROUGH

> Mail Address : 5401 W. KENNEDY BLVD.

> City : TAMPA State: FL ZIP Code: 33609

> -

> SIC Description

> 0000 Not on table

Officer : CONTACT UNKNOWN

> 0000 Not on table

Title :

> 0000 Not on table

Telephone : - -

> 0000 Not on table

Date Signed: 04/29/1991

>

>

>

> Ms. Carol L. Buckingham

> Agriculture Division (2225A)>

> Office of Compliance

> Office of Enforcement and Compliance Assurance

> 1200 Pennsylvania Avenue, NW (Room 6102)

> Washington, DC 20460 (regular mail) 20004 (courier delivery)

> tel # 202-564-5008

> fax # 202-564-0085

> email: [buckingham.carol@epa.gov](mailto:buckingham.carol@epa.gov)

>



1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

PHONE: 703-492-0445  
FAX: 703-492-0668

WEB SITES: [www.chemreg.com](http://www.chemreg.com)  
[www.pesticide.net](http://www.pesticide.net)

**FAX MESSAGE**

DATE: 5/17/2005

TO: Hope Johnson, EPA-OPP

FAX: 703-308-1825

FROM: Bob Butz

PAGES: 3 (Including Cover)

**MESSAGE:**

Hope,

The corrected page of the data matrix for 70552-R, both public and Agency versions follow.

Please call or email me if you need anything further.

-- Bob Butz

Robert Butz, Ph.D.  
ChemReg International  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

Phone: 703-492-0541  
Fax: 703-492-0668  
Email: [butz@chemreg.com](mailto:butz@chemreg.com)

**THIS WILL BE THE ONLY FORM OF DELIVERY OF THIS DOCUMENT**

**CONFIDENTIALITY NOTICE**

*The information in this facsimile is confidential and intended only for the use of the addressee. Do not copy or distribute to anyone other than the addressee. Reliance on these data by other than the intended recipient is prohibited. Please notify us immediately if you received this communication in error. Upon notification, we will arrange for return of fax copies. Thank you for your assistance.*

Reviewed label

**Paraquat Technical Concentrate**

For Formulation of Paraquat Herbicide Products Only

**ACTIVE INGREDIENT**

Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride) ..... 46.2%

**INERT INGREDIENTS** ..... 53.8%

**TOTAL** ..... 100.0%

Contains 3.16 pounds paraquat cation per gallon

Contains emetic.

EPA Reg. No. 70552-R

EPA Establishment No. 70552-TWN-001

**KEEP OUT OF REACH OF CHILDREN**

**DANGER - PELIGRO**



**POISON**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

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| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <ul style="list-style-type: none"> <li>• SPEED IS ESSENTIAL. Immediate medical attention is required. If available, give an adsorbent such as activated charcoal, bentonite or Fuller's Earth.</li> <li>• Call a poison control center or doctor immediately for treatment.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                           |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 to 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>                                                                                                                   |
| If Inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance.</li> <li>• Call a poison control center or doctor for further treatment advice</li> </ul>                                                                                                                             |
| NOTE TO PHYSICIAN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                           |
| <p>Refer to the booklet 'Paraquat Poisoning. A Practical Guide to Diagnosis, First Aid and Hospital Treatment'. (<a href="http://www.syngenta.com/pqmedguide/">http://www.syngenta.com/pqmedguide/</a>) Administer either activated charcoal (100g for adults or 2g/kg body weight in children) or Fuller's Earth (15% solution; 1 liter for adults or 15mg/kg body weight in children).</p> <p>NOTE: The use of gastric lavage without administration of an adsorbent has not shown any clinical benefit. Do not use supplemental oxygen. Eye splashes from concentrated material should be treated by an eye specialist after initial treatment. With the possibility of late onset corneal ulceration, it is advised that patients with paraquat eye injuries are reviewed by an eye specialist the day after first presentation. Use treatment that is appropriate for chemical burns. Intact skin is an effective barrier to paraquat, however contact with irritated or cut skin or repeated contact with intact skin may result in poisoning.</p> |                                                                                                                                                                                                                                                                                                                                                           |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                           |
| HOTLINE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                           |
| For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                           |

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER – POISON**



May be fatal if swallowed. Fatal if inhaled. Do not breathe spray mist. Do not inhale contaminated dust. Causes irreversible eye damage. Wear [goggles, face shield, or safety glasses]. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin.

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
  - Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)
  - Full face shield
  - Chemical-resistant gloves, Category A
  - Chemical resistant apron and shoes plus socks
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

**ENVIRONMENTAL HAZARDS**

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

**PHYSICAL AND CHEMICAL HAZARD**

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

**SPILLAGE DURING TRANSPORT**

**Emergency Action:** Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

**KEEP PUBLIC AND ANIMALS** away from area. **MARK ROADS AND WARN OTHER ROAD USERS.**  
**WEAR** face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into a herbicide for the following uses:

### (1) TERRESTRIAL FOOD CROP

acerola (West Indies cherry); apricot; asparagus; avocado; banana; blackberry; blueberry; boysenberry; broccoli; cabbage; cabbage, Chinese; carrot (including tops); cauliflower; cherry; cocoa; coffee; collards; cucumber; eggplant; fig; filbert (hazelnut); garlic; groundcherry (strawberry tomato/tomatillo); guava; hops; kiwifruit; lettuce; loquat; macadamia nut (bushnut); manioc (cassava); melons; melons, cantaloupe; melons, musk; melons, water; mint; nectarine; olive; onion; papaya; passion fruit; peach; pear; pecan; pepino (melonpear); pepper; pepper (chili type); pineapple; pistachio; plum; potato, white/Irish; prune; pumpkin; raspberry (black, red); rhubarb; smallfruits; squash (all or unspecified); strawberry; sugarbeet; taro; walnut (English/black); yam; yautia

### (2) TERRESTRIAL FOOD+FEED CROP

almond; apple; barley; beans, asparagus; beans, dried-type; beans, mung; beans, succulent (lima); beans, succulent (snap); citrus fruits; corn (unspecified); corn, field; corn, pop; corn, sweet; cotton (unspecified); garbanzos (including chickpeas); grapes; guar; hops; legume vegetables; mint; oats; orchards (unspecified); peanuts; peanuts (unspecified); peas (unspecified); peas, field; peas, pigeon; peppermint; potato, white/Irish; safflower; safflower (unspecified); small fruits; small grains (unspecified); sorghum; sorghum (unspecified); soybeans (unspecified); soybeans, edible; spearmint; sugarbeet; sugar crops; sugarcane; sunflower; tomato; turnip; vegetables (unspecified); wheat

### (3) TERRESTRIAL FEED CROP

alfalfa; barley; beans; clover; crownvetch; legume vegetables; lespedeza; lupine; pastures; sainfoin; timothy; trefoil; tyfon; vetch; wheat

### (4) TERRESTRIAL NON-FOOD CROP

agricultural fallow/idleland; airports/landing fields; commercial/industrial lawns; commercial/institutional/industrial; premises/equipment (outdoor); fencerows/hedgerows; grasses grown for seed; industrial areas (outdoor); jojoba; nonagricultural outdoor buildings/structures; nonagricultural uncultivated areas/soils; ornamental and/or shade trees; peach (non-bearing, seed beds); recreation area lawns; tomato (post-harvest); wood protection treatment to forest products (seasoned)

### (5) FORESTRY

forest plantings (reforestation programs); pine (forest/shelterbelt); shelterbelt plantings

**(6) TERRESTRIAL NON-FOOD**

ornamental and/or shade trees; ornamental herbaceous plants;  
ornamental woody shrubs and vines; non-crop areas such as public  
airports, electric transformer stations and around commercial buildings

**(7)** Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted  
in support of registration; and

**(8)** Uses for experimental purposes that are in compliance with USEPA requirements.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking  
water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with  
any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate  
is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact  
your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA  
Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and  
dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

**WARRANTY STATEMENT**

SINON CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for  
purposes stated on such label only when used in accordance with directions under normal use conditions. It is  
impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by  
Buyer and User. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or  
damages resulting from or in any way arising from the use, handling, or application of this product, whether in  
contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this  
product. SINON CORP. makes no warranties of merchantability or of fitness for a particular purpose nor for any  
other expressed or implied warranty except as stated above.

Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 04-19-2005. NOT EPA APPROVED



EPA Registration No. 70552-1

Page \_\_\_\_\_ is not included in this copy.

Pages 61 through 72 are not included in this copy.

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The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) \_\_\_\_\_.
- ☐ The document is not responsive to the request.
- ☒ Records claimed as confidential business information.

---

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---

## AMENDMENT TO THE PRODUCT CHEMISTRY REVIEW

DATE: 16/MAY/2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGA/MP [X] EP [ ]  
DP BARCODE No.: D316933 REG. No.: 70552-R  
PRODUCT NAME: Paraquat Technical Concentrate  
COMPANY: Sinon Corporation  
PCC: 061601; Decision No.: 339337; FOOD USE [X]  
INTEGRATED FORMULATION: Yes [X] NO [ ]

FROM: Shyam B. Mathur,  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505C)

*S. B. Mathur*  
*5716105*  
*mc*

TO: Hope Johnson / James Tompkins, RM 25  
Herbicide Branch/RD(7505C)

### INTRODUCTION

The product chemistry data for Paraquat technical concentrate was reviewed previously (see PCR dated July 1, 2004; D299077). In a Agency's letter of July 8, 2004, the registrant was informed of several deficiencies in the product chemistry data. The deficiencies pertained principally to 830 series Subgroup A. The registrant responded on July 31, 2004 and submitted the required data under MRID No. 463312-01 as a supplemental report to previous data with MRID No. 460988-01. The TRB has been asked to evaluate the supplemental report submitted.

### SUMMARY OF FINDINGS

1. The Paraquat technical concentrate has the product label claim of 46.2%.
2. 830.1550 (product identity & composition): a revised CSF for basic formulation (dated 07-28-04) was submitted as per recommendation of the Agency. The CSF is filled out correctly & completely. The nominal concentration of the active ingredient concurs with the product label claim of 46.2% in compliance with PR Notice 91-2. The data submitted satisfy the data requirements of 40CFR§158.155.
3. 830.1620 (description of production process): additional information have been provided on the integrated production process. The additional information included the information on the reactors & equipments, the amounts of starting materials used and the reaction conditions and the flow diagram of the manufacturing process. The registrant has also described the quality control process which resulted in the consistence purity of the AI in different batches. The data submitted satisfy the data requirements of 40CFR§158.162.
4. 830.1750 (certified limits): the registrant has provided the explanation for the proposed expanded certified limits for one of the inert ingredients. According to the registrant the proposed certified limits are based on the consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures were used and allow for all sources of variability likely to be encountered in the production process. The amount of the solvent in the final product may be adjusted to ensure that the active ingredient assay is within the proposed limits. The data submitted satisfy the data requirements of 40CFR§158.175.
5. 830.1670 (discussion on the formation of impurities): sufficient details have been provided on this topic. The registrant has described the mechanism for the formation of impurities and all the impurities present at the levels of > 0.1% have been identified and quantified.

DP BARCODE No.: D316933 REG. No.: 70552-R PRODUCT NAME: Paraquat Technical Concentrate

**CONCLUSIONS**

The TRB has reviewed the supplemental data submitted for 830 series Subgroup A and has concluded that:

1. The product chemistry data submitted corresponding to guideline 830.1550 (product identity & composition) satisfy the data requirements of 40CFR§158.155. The revised CSF for basic formulation dated July 28, 2004 is acceptable.
2. The data submitted corresponding to guideline 830.1620 (description of production process) satisfy the data requirements of 40CFR§158.162 and are acceptable.
3. The data submitted corresponding to guideline 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.175 and are acceptable. The justifications provided for expanded certified limits in case of one of the inert ingredient are acceptable.
4. The product chemistry data submitted corresponding to guidelines 830.1670 (discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.167 and are acceptable.

---

Registration NO. 70552-1

---

Page \_\_\_\_\_ is not included in this copy.

Pages 75 through 76 are not included in this copy.

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The material not included contains the following type of information:

- \_\_\_\_\_ Identity of product inert ingredients.
  - \_\_\_\_\_ Identity of product impurities.
  - ☒ Description of the product manufacturing process.
  - \_\_\_\_\_ Description of quality control procedures.
  - \_\_\_\_\_ Identity of the source of product ingredients.
  - \_\_\_\_\_ Sales or other commercial/financial information.
  - \_\_\_\_\_ A draft product label.
  - \_\_\_\_\_ The product confidential statement of formula.
  - \_\_\_\_\_ Information about a pending registration action.
  - \_\_\_\_\_ FIFRA registration data.
  - \_\_\_\_\_ The document is a duplicate of page(s) \_\_\_\_\_.
  - \_\_\_\_\_ The document is not responsive to the request.
- 

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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## AMENDMENT TO THE PRODUCT CHEMISTRY REVIEW

DATE: 16/MAY/2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGA/MP [X] EP ☐  
DP BARCODE No.: D316933 REG. No.: 70552-R  
PRODUCT NAME: Paraquat Technical Concentrate  
COMPANY: Sinon Corporation  
PCC: 061601; Decision No.: 339337; FOOD USE [X]  
INTEGRATED FORMULATION: Yes [X] NO ☐

FROM: Shyam B. Mathur,  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505C)

*S. B. Mathur*  
*5/16/05*

TO: Hope Johnson / James Tompkins, RM 25  
Herbicide Branch/RD(7505C)

### INTRODUCTION

The product chemistry data for Paraquat technical concentrate was reviewed previously (see PCR dated July 1, 2004; D299077). In a Agency's letter of July 8, 2004, the registrant was informed of several deficiencies in the product chemistry data. The deficiencies pertained principally to 830 series Subgroup A. The registrant responded on July 31, 2004 and submitted the required data under MRID No. 463312-01 as a supplemental report to previous data with MRID No. 460988-01. The TRB has been asked to evaluate the supplemental report submitted.

### SUMMARY OF FINDINGS

1. The Paraquat technical concentrate has the product label claim of 46.2%.
2. 830.1550 (product identity & composition): a revised CSF for basic formulation (dated 07-28-04) was submitted as per recommendation of the Agency. The CSF is filled out correctly & completely. The nominal concentration of the active ingredient concurs with the product label claim of 46.2% in compliance with PR Notice 91-2. The data submitted satisfy the data requirements of 40CFR§158.155.
3. 830.1620 (description of production process): additional information have been provided on the integrated production process. The additional information included the information on the reactors & equipments, the amounts of starting materials used and the reaction conditions and the flow diagram of the manufacturing process. The registrant has also described the quality control process which resulted in the consistence purity of the AI in different batches. The data submitted satisfy the data requirements of 40CFR§158.162.
4. 830.1750 (certified limits): the registrant has provided the explanation for the proposed expanded certified limits for one of the inert ingredients. According to the registrant the proposed certified limits are based on the consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures were used and allow for all sources of variability likely to be encountered in the production process. The amount of the solvent in the final product may be adjusted to ensure that the active ingredient assay is within the proposed limits. The data submitted satisfy the data requirements of 40CFR§158.175.
5. 830.1670 (discussion on the formation of impurities): sufficient details have been provided on this topic. The registrant has described the mechanism for the formation of impurities and all the impurities present at the levels of > 0.1% have been identified and quantified.

DP BARCODE No.: D316933 REG. No.: 70552-R PRODUCT NAME: Paraquat Technical Concentrate

CONCLUSIONS

The TRB has reviewed the supplemental data submitted for 830 series Subgroup A and has concluded that:

1. The product chemistry data submitted corresponding to guideline 830.1550 (product identity & composition) satisfy the data requirements of 40CFR§158.155. The revised CSF for basic formulation dated July 28, 2004 is acceptable.
2. The data submitted corresponding to guideline 830.1620 (description of production process) satisfy the data requirements of 40CFR§158.162 and are acceptable.
3. The data submitted corresponding to guideline 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.175 and are acceptable. The justifications provided for expanded certified limits in case of one of the inert ingredient are acceptable.
4. The product chemistry data submitted corresponding to guidelines 830.1670 (discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.167 and are acceptable.

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Registration File NO. 70552-1

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Pages 79 through 80 are not included in this copy.

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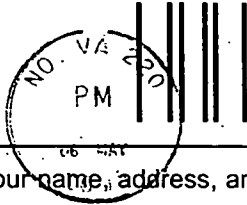
The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
  - ☐ Identity of product impurities.
  - ☒ Description of the product manufacturing process.
  - ☐ Description of quality control procedures.
  - ☐ Identity of the source of product ingredients.
  - ☐ Sales or other commercial/financial information.
  - ☐ A draft product label.
  - ☐ The product confidential statement of formula.
  - ☐ Information about a pending registration action.
  - ☐ FIFRA registration data.
  - ☐ The document is a duplicate of page(s) \_\_\_\_\_.
  - ☐ The document is not responsive to the request.
- 

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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UNITED STATES POSTAL SERVICE



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• Sender: Please print your name, address, and ZIP+4 in this box •

Hope A. Johnson  
US, EPA  
Registration Division (7505C)  
1200 Pennsylvania Ave NW  
Washington DC 20460



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Sent May 2

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Street, Apt. No., or PO Box No. 190 Old Bridge Rd Suite 201  
City, State, ZIP+4 Sale Ridge, VA 22192

PS Form 3800, May 2000 See Reverse for Instructions

7000 1670 0012 8257 2475



# SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

## 1. Article Addressed to:

Robert G. Butz  
Chen Reg International LLC  
1970 Old Bridge Rd Suite  
201  
Lake Ridge, VA 22192-7383

## 2. Article Number

(Transfer from service label)

7000 1670 0012 8257 2475

# COMPLETE THIS SECTION ON DELIVERY

## A. Signature

X *Butz*

☐ Agent

☐ Addressee

## B. Received by (Printed Name)

## C. Date of Delivery

5/6/98

## D. Is delivery address different from item 1?

☐ Yes

If YES, enter delivery address below: ☐ No

## 3. Service Type

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☐ Express Mail

☐ Registered

☐ Return Receipt for Merchandise

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PS Form 3811, August 2001

Domestic Return Receipt

102595-01-M-0381

## Certified Mail Provides:

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- Certified Mail may ONLY be combined with First-Class Mail or Priority Mail.
- Certified Mail is not available for any class of international mail.
- NO INSURANCE COVERAGE IS PROVIDED with Certified Mail. For valuables, please consider Insured or Registered Mail.
- For an additional fee, a Return Receipt may be requested to provide proof of delivery. To obtain Return Receipt service, please complete and attach a Return Receipt (PS Form 3811) to the article and add applicable postage to cover the fee. Endorse mailpiece "Return Receipt Requested". To receive a fee waiver for a duplicate return receipt, a USPS postmark on your Certified Mail receipt is required.
- For an additional fee, delivery may be restricted to the addressee or addressee's authorized agent. Advise the clerk or mark the mailpiece with the endorsement "Restricted Delivery".
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IMPORTANT: Save this receipt and present it when making an inquiry.

PS Form 3800, May 2000 (Reverse)

102595-99-M-2037



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAY 2 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Mr. Robert G. Butz  
ChemReg International, LLC  
Consultant for: Sinon Corporation  
1990 Old Bridge Rd, Suite 201  
Lake Ridge, VA 22192-2383

Dear Mr. Butz:

Subject: Paraquat Technical Concentrate  
EPA Registration Number 70552-R  
Product Registration Status

As of May 2, 2005, all requirements have been satisfied concerning the registration of EPA File Symbol Number 70552-R, except for the following

- a) Guideline 830.6317: One Year Storage Stability Study.
- b) Guideline 830.6320: Corrosion Characteristics Study.
- c) Data Matrix Corrections Needed:
  - i) Page 3, 870.3465 90 Day Inhalation -rodent, add Syngenta to the Submitter column
  - ii) Page 3, 870.4100 Chronic feeding nonrodent, add Syngenta to the Submitter column
  - iii) Page 3, 870.5100 Gene mutation (Ames Test), change Syngenta to Scotts in the Submitter column
  - iv) Page 3, 84-2B Structural Chromosomal effects, add Scotts to Submitter column
  - v) Page 4, 84-4 Other genotoxic effects, change 152693 to 15293, and add Scotts to the Submitter column
  - vi) Page 5, 850.1075 Fish Toxicity Bluegill, add U.S. FWS to the Submitter column and remove Syngenta.
  - vii) Page 5, 850.1010 Invertebrate toxicity, remove US EPA and US FWS from the submitter column
- d) The Certification with Respect To Citation Of Data form 8570-34, and the appropriate offer-to-pay letters.

Both the One Year Storage Stability study and the Corrosion Characteristics study will be considered conditions of registration. However, the Certification with Respect to Citation of Data form must be submitted before registration of EPA File Symbol 70552-R can be granted.

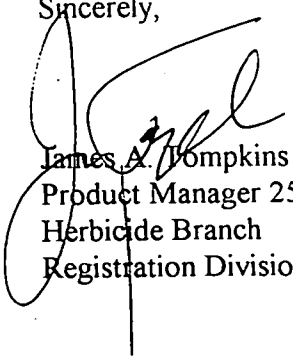
May 2, 2005

In a letter dated April 22, 2005 from Robert G. Butz of ChemReg International, LLC, it was requested that Sinon Corporation not be required to cite the Ag Reentry Task Force (ARTF) or the Outdoor Residential Exposure Task Force (ORETF) data on the data matrix. [The letter also stated that the Certification with Respect to Citation of Data form would be withheld until this issue was settled.] **The Agency agrees with this argument, and Sinon Corporation will not be required to cite either ARTF or ORETF on the data matrix.**

Therefore, since all issues brought up by ChemReg International LLC have been resolved, you have **7 business days** from the date of this letter (i.e., **May 11, 2005**) to either submit the outstanding Certification with Respect to Citation of Data form and an updated Data Matrix including the changes outlined above, or withdraw the pending registration, or else the Agency may issue a Notice of Intent to Deny this pending registration action.

If you have any questions, please contact Hope Johnson at 703-305-5410.

Sincerely,



James A. Tompkins  
Product Manager 25  
Herbicide Branch  
Registration Division (7505C)

Reviewed updated label

**Paraquat Technical Concentrate**

For Formulation of Paraquat Herbicide Products Only

**ACTIVE INGREDIENT**

Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride) ..... 46.2%

**INERT INGREDIENTS** ..... 53.8%

**TOTAL** ..... 100.0%

Contains 3.16 pounds paraquat cation per gallon ✓

Contains emetic.

EPA Reg. No. 70552-R

EPA Establishment No. 70552-TWN-001

**KEEP OUT OF REACH OF CHILDREN**

**DANGER – PELIGRO**



**POISON**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <ul style="list-style-type: none"><li>• SPEED IS ESSENTIAL. Immediate medical attention is required. If available, give an adsorbent such as activated charcoal, bentonite or Fuller's Earth.</li><li>• Call a poison control center or doctor immediately for treatment.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul> |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>                                                          |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes.</li><li>• Call a poison control center or doctor for treatment advice</li></ul>                                                                                                                   |
| If Inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance.</li><li>• Call a poison control center or doctor for further treatment advice</li></ul>                                                                                                                             |
| NOTE TO PHYSICIAN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                       |
| <p>Refer to the booklet 'Paraquat Poisoning. A Practical Guide to Diagnosis, First-Aid and Hospital Treatment'. (<a href="http://www.syngenta.com/pqmedguide/">http://www.syngenta.com/pqmedguide/</a>) Administer either activated charcoal (100g for adults or 2g/kg body weight in children) or Fuller's Earth (15% solution; 1 liter for adults or 15mg/kg body weight in children).</p> <p>NOTE: The use of gastric lavage without administration of an adsorbent has not shown any clinical benefit. Do not use supplemental oxygen. Eye splashes from concentrated material should be treated by an eye specialist after initial treatment. With the possibility of late onset corneal ulceration, it is advised that patients with paraquat eye injuries are reviewed by an eye specialist the day after first presentation. Use treatment that is appropriate for chemical burns. Intact skin is an effective barrier to paraquat, however contact with irritated or cut skin or repeated contact with intact skin may result in poisoning.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> |                                                                                                                                                                                                                                                                                                                                                       |
| HOTLINE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                       |
| For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                       |

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER – POISON**



May be fatal if swallowed. Fatal if inhaled. Do not breathe spray mist. Do not inhale contaminated dust. Causes irreversible eye damage. Wear [goggles, face shield, or safety glasses]. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. ✓

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
  - Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)
  - Full face shield
  - Chemical-resistant gloves, Category A
  - Chemical resistant apron and shoes plus socks ✓
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

**ENVIRONMENTAL HAZARDS**

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

**PHYSICAL AND CHEMICAL HAZARD**

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

**SPILLAGE DURING TRANSPORT**

**Emergency Action:** Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

**KEEP PUBLIC AND ANIMALS** away from area. **MARK ROADS AND WARN OTHER ROAD USERS.**  
**WEAR** face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

## DIRECTIONS FOR USE


It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into a herbicide for the following uses:


### (1) TERRESTRIAL FOOD CROP

acerola (West Indies cherry); apricot; asparagus; avocado; banana; blackberry; blueberry; boysenberry; broccoli; cabbage; cabbage, Chinese; carrot (including tops); cauliflower; cherry; cocoa; coffee; collards; cucumber; eggplant; fig; filbert (hazelnut); garlic; groundcherry (strawberry tomato/tomatillo); guava; hops; kiwifruit; lettuce; loquat; macadamia nut (bushnut); manioc (cassava); melons; melons, cantaloupe; melons, musk; melons, water; mint; nectarine; olive; onion; papaya; passion fruit; peach; pear; pecan; pepino (melonpear); pepper; pepper (chili type); pineapple; pistachio; plum; potato, white/Irish; prune; pumpkin; raspberry (black, red); rhubarb; smallfruits; squash (all or unspecified); strawberry; sugarbeet; taro; walnut (English/black); yam; yautia




### (2) TERRESTRIAL FOOD+FEED CROP

almond; apple; barley; beans, asparagus; beans, dried-type; beans, mung; beans, succulent (lima); beans, succulent (snap); citrus fruits; corn (unspecified); corn, field; corn, pop; corn, sweet; cotton (unspecified); garbanzos (including chickpeas); grapes; guar; hops; legume vegetables; mint; oats; orchards (unspecified); peanuts; peanuts (unspecified); peas (unspecified); peas, field; peas, pigeon; peppermint; potato, white/Irish; safflower; safflower (unspecified); small fruits; small grains (unspecified); sorghum; sorghum (unspecified); soybeans (unspecified); soybeans, edible; spearmint; sugarbeet; sugar crops; sugarcane; sunflower; tomato; turnip; vegetables (unspecified); wheat




### (3) TERRESTRIAL FEED CROP

alfalfa; barley; beans; clover; crownvetch; legume vegetables; lespedeza; lupine; pastures; sainfoin; timothy; trefoil; tyfon; vetch; wheat




### (4) TERRESTRIAL NON-FOOD CROP

agricultural fallow/idleland; airports/landing fields; commercial/industrial lawns; commercial/institutional/industrial; premises/equipment (outdoor); fencerows/hedgerows; grasses grown for seed; industrial areas (outdoor); jojoba; nonagricultural outdoor buildings/structures; nonagricultural uncultivated areas/soils; ornamental and/or shade trees; peach (non-bearing, seed beds); recreation area lawns; tomato (post-harvest); wood protection treatment to forest products (seasoned)



### (5) FORESTRY

forest plantings (reforestation programs); pine (forest/shelterbelt); shelterbelt plantings



**(6) TERRESTRIAL NON-FOOD**

ornamental and/or shade trees; ornamental herbaceous plants;  
ornamental woody shrubs and vines; non-crop areas such as public  
airports, electric transformer stations and around commercial buildings ✓

**(7)** Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted  
in support of registration; and

**(8)** Uses for experimental purposes that are in compliance with USEPA requirements.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

**WARRANTY STATEMENT**

SINON CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by Buyer and User. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this product. SINON CORP. makes no warranties of merchantability or of fitness for a particular purpose nor for any other expressed or implied warranty except as stated above.

Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 04-19-2005. NOT EPA APPROVED



EPA Registration No. 70552-1

Page \_\_\_\_\_ is not included in this copy.

Pages 90 through 101 are not included in this copy.

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The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) \_\_\_\_\_.
- ☐ The document is not responsive to the request.
- ☒ Records claimed as confidential business information.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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## Data Supporting Guideline Requirements for the Reregistration of Paraquat Dichloride

| REQUIREMENT                                            | USE PATTERN | CITATION(S)                                     |
|--------------------------------------------------------|-------------|-------------------------------------------------|
| 85-2 Dermal Penetration                                | A,B,C,J     | 00126096, 00126097, 00126098 00126099, 00153439 |
| 86-1 Domestic Animal Safety                            |             | Not required                                    |
| <b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>        |             |                                                 |
| 132-1A Foliar Residue Dissipation                      |             | Not required                                    |
| 132-1B Soil Residue Dissipation                        |             | Waived                                          |
| 133-3 Dermal Passive Dosimetry Exposure                |             | Waived                                          |
| 133-4 Inhalation Passive Dosimetry Exposure            |             | Waived                                          |
| 231 Estimation of Dermal Exposure at Outdoor Sites     |             | Not required                                    |
| 232 Estimation of Inhalation Exposure at Outdoor Sites |             | Not required                                    |
| 233 Estimation of Dermal Exposure at Indoor Sites      |             | Not required                                    |
| 234 Estimation of Inhalation Exposure at Indoor Sites  |             | Not required                                    |
| <b><u>ENVIRONMENTAL FATE</u></b>                       |             |                                                 |
| 160-5 Chemical Identity                                |             | Not required                                    |
| 161-1 Hydrolysis                                       | A,B,C,J     | Upton <sup>3</sup>                              |

Guideline fulfilled; No MRID #'s for this study - review dated 2/14/85



Robert Butz  
<butz@chemreg.com>  
03/28/2005 06:11 PM

To Jim Tompkins/DC/USEPA/US@EPA  
cc Hope Johnson/DC/USEPA/US@EPA  
bcc  
Subject Paraquat technical Registration of Sinon

Jim and Hope.

I am preparing the data matrix for Sinon's technical product and I notice on the handout you provided last week that you are asking Sinon to list both the Ag Reentry Task Force (ARTF) and the Outdoor Residential Exposure Task Force (ORETF) as data requirements for this registration. I realize both these Task Forces are listed on the data submitters list under paraquat dichloride but I don't believe either is a legitimate listing.

I believe listing ORETF on the data matrix is not required because there are no residential uses for paraquat. The paraquat RED did not consider residential use patterns for paraquat because there are no such products or uses. Because paraquat is a restricted use pesticide (RUP) there will likely never be any residential use products. Furthermore, Sinon does not want this use pattern on their technical label. I also realize paraquat dichloride is listed on the Residential Exposure DCI of March 1995. However, the uses Sinon has requested on its technical label do not include any residential uses that would trigger the need for data developed by the ORETF. Therefore, we believe Sinon should not need to cite the ORETF on their data matrix for this product.

As for the ARTF, I realize the Ag Reentry DCI of October 1995 lists paraquat dichloride as a chemical subject to the DCI, but in the 1997 paraquat RED it states on page 57 that for "Additional Occupational/Residential Exposure Studies Handler Studies: None are necessary". There was sufficient data available to conduct an occupational risk assessment and decide reentry intervals without the ARTF data. Additionally, the RED identifies that all data requirements associated with re-entry (EPA Guidelines 132-1, 133-3, 133-4) and occupational/residential exposure (EPA Guidelines 231, 232, 233, 234) are either waived or not required. Therefore, we believe Sinon does not need to cite the ARTF on their data matrix.

Please let me know if you agree with these assessments.

-- Bob Butz

Robert Butz, Ph.D.  
ChemReg International  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

March 23, 2005 1-2pm

**1. Certification with Respect to Citation of Data**

A. Still outstanding, must submit ASAP.

**2. Data Matrix:** (Depends on Cert.: Whether doing Cite-all or Selective Method)

A. Correct MRID's on current Data Matrix and add your own product chemistry and acute tox MRIDS. Add ~~Agricultural Reentry~~ Task Force and ~~Outdoor Residential Exposure~~ Task Force, members of the ~~PDSL~~ for paraquat, after listing generic MRID's.

Incorrect MRIDs:

870.3465: remove incorrect MRIDS, replace with 00030788, 00113718

870.4100: Add Zeneca to Submitter under Chronic feeding nonrodent.

870.4200: change 152332 to 153223

84-4: change 100422 to 100442

870.7485: change 35297 to 36297

850.4225: change GS262-028 to GS0262-028

850.1075: for guidelines Fish toxicity rainbow trout and invertebrate toxicity, remove Syngenta and Zeneca from the submitter column, and add "U.S. FWS and U.S. EPA"

*change Zeneca to Syngenta.*

B. Possibility #2: Remove all generic MRID's and replace with sentence "Cite-all for generic data requirements per 1997 Paraquat Dichloride RED" (appendix B). Add the product chemistry and acute tox MRIDS for 70552-R. List ALL the members of the PDSL for paraquat on the data matrix after the generic data statement.

**3. Label**

A. Statement says "Contains 3 lbs paraquat cation per gallon" for your product at 46.2%

a.i. Syngenta's says "3.14 lbs paraquat cation per gallon" at 45.6% a.i. ?????

B. Add "contains emetic" after Ingredient Statement

C. Update First Aid statements to match Syngenta's language on 100-1067. (Including Note To Physician)

D. Change Precautionary Statements to the following:

"May be fatal if swallowed. Fatal if inhaled. Do not breathe spray mist. Do not inhale contaminated dust. Causes irreversible eye damage. Wear [goggles, face shield, or safety glasses]. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin."

E. Change "apron and waterproof footwear" to "chemical resistant apron and shoes plus socks" after Precautionary Statements.

F. Use classifications

i. Change to RED listings on page 3 of the RED. Change "Tylon" to "Tyfon"



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## DATA MATRIX

|                                                                                                                                       |                          |             |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 1 of 7 |
| Product: Paraquat Technical Concentrate                                                                                               |                          |             |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          |             |
| Ingredient: paraquat dichloride                                                                                                       |                          |             |

UNACCEPTABLE

| Guideline Reference Number | Guideline Study Name                          | MRID Number | Submitter   | Status | Note       |
|----------------------------|-----------------------------------------------|-------------|-------------|--------|------------|
| 830.1550                   | Product identity and composition              |             | Sinon Corp. | Own    |            |
| 830.1600                   | Starting materials                            |             | Sinon Corp. | Own    |            |
| 830.1620                   | Method of manufacture                         |             | Sinon Corp. | Own    |            |
| 830.1670                   | Discussion of formation of impurities         |             | Sinon Corp. | Own    |            |
| 830.1700                   | Preliminary analysis                          |             | Sinon Corp. | Own    |            |
| 830.1750                   | Certification of limits                       |             | Sinon Corp. | Own    |            |
| 830.1800                   | Enforcement analytical method                 |             | Sinon Corp. | Own    |            |
| 830.6302                   | Color                                         |             | Sinon Corp. | Own    |            |
| 830.6303                   | Physical state                                |             | Sinon Corp. | Own    |            |
| 830.6304                   | Odor                                          |             | Sinon Corp. | Own    |            |
| 830.6313                   | Stability to normal and elevated temperatures |             | Sinon Corp. | Own    | NA per RED |
| 830.6314                   | Oxidation/reduction                           |             | Sinon Corp. | Own    | NA per RED |
| 830.6315                   | Flammability                                  |             | Sinon Corp. | Own    | NA per RED |
| 830.6316                   | Explosibility                                 |             | Sinon Corp. | Own    | NA per RED |
| 830.6317                   | Storage stability                             |             | Sinon Corp. | Own    | NA per RED |
| 830.6319                   | Miscibility                                   |             | Sinon Corp. | Own    | NA per RED |
| 830.6320                   | Corrosion characteristics                     |             | Sinon Corp. | Own    | NA per RED |
| 830.6321                   | Dielectric breakdown voltage                  |             | Sinon Corp. | Own    | NA per RED |
| 830.7000                   | pH                                            |             | Sinon Corp. | Own    |            |
| 830.7050                   | UV/visible absorption                         |             | Sinon Corp. | Own    | NA per RED |
| 830.7100                   | Viscosity                                     |             | Sinon Corp. | Own    |            |
| 830.7200                   | Melting point                                 |             | Sinon Corp. | Own    |            |

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
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| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 2 of 7                             |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          | Product: Paraquat Technical Concentrate |
| Ingredient: paraquat dichloride                                                                                                       |                          |                                         |

| Guideline Reference Number | Guideline Study Name       | MRID Number      | Submitter          | Status | Note                  |
|----------------------------|----------------------------|------------------|--------------------|--------|-----------------------|
| 830.7220                   | Boiling point              |                  | Sinon Corp.        | Own    | NA per RED            |
| 830.7300                   | Density                    |                  | Sinon Corp.        | Own    |                       |
| 830.7370                   | Dissociation constant      |                  | Sinon Corp.        | Own    |                       |
| 830.7550                   | Partition coefficient      |                  | Sinon Corp.        | Own    |                       |
| 830.7840                   | Solubility                 |                  | Sinon Corp.        | Own    |                       |
| 830.7950                   | Vapor pressure             |                  | Sinon Corp.        | Own    |                       |
| 870.1100                   | Acute oral toxicity        | 43685001         | Zeneca             | Pay    |                       |
| 870.1200                   | Acute dermal toxicity      |                  | Sinon Corp.        | Own    |                       |
| 870.1300                   | Acute inhalation toxicity  |                  | Sinon Corp.        | Own    |                       |
| 870.2400                   | Eye irritation             |                  | Sinon Corp.        | Own    |                       |
| 870.2500                   | Dermal irritation          |                  | Sinon Corp.        | Own    |                       |
| 870.2600                   | Dermal sensitization       |                  | Sinon Corp.        | Own    |                       |
| 870.3150                   | 90-day feeding non-rodent  | 72416            | Scotts Co.         | Old    |                       |
| 870.3200                   | 21-day dermal toxicity     | 156313           | Scotts Co.         | Old    |                       |
| 870.3465                   | 90-day inhalation - rodent | 138657, 40218091 | Scotts Co., Zeneca | Old    | 3078801d<br>11371801d |
| 870.4100                   | Chronic feeding rodent     | 138657, 40218091 | Scotts Co., Zeneca | Old    | Corrected             |
| 870.4100                   | Chronic feeding nonrodent  | 432474           | Scotts Co., Zeneca | Old    |                       |

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
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|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 3 of 7                             |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          | Product: Paraquat Technical Concentrate |
| Ingredient: paraquat dichloride                                                                                                       |                          |                                         |

| Guideline Reference Number | Guideline Study Name            | MRID Number                                                                                       | Submitter                | Status   | Note |
|----------------------------|---------------------------------|---------------------------------------------------------------------------------------------------|--------------------------|----------|------|
| 870.4200                   | Carcinogenicity - rat           | 138637-01<br>452332-15<br>40183501-15<br>40202401-15<br>40202402-15<br>41317401-15<br>40218001-15 | Zeneca<br>153223         | Old/pay  |      |
| 870.4200                   | Carcinogenicity - mouse         | 87924,<br>40202403                                                                                | Scotts, Zeneca           | Old/publ |      |
| 870.3700                   | Developmental toxicity - rat    | 113714                                                                                            | Scotts                   | Old      |      |
| 870.3700                   | Developmental toxicity - rabbit | 96338                                                                                             | Scotts                   | Old      |      |
| 870.3800                   | 2-generation reproduction - rat | 126783                                                                                            | Scotts                   | Old      |      |
| 870.5100                   | Gene mutation (Ames test)       | 152690,<br>152691                                                                                 | Scotts                   | Old      |      |
| 84-2B                      | Structural chromosomal effects  | 73487, 152692,<br>40202404                                                                        | Scotts, Zeneca           | Old      |      |
| 84-4                       | Other genotoxic effects         | 15293, 100422,<br>152695,<br>40202405                                                             | Scotts, Zeneca<br>100442 | Old      |      |
| 870.7485                   | General metabolism              | 28597, 35297,<br>28598, 55107,<br>28599, 126096                                                   | Scotts<br>36297          | Old      |      |

Signature

*Judith W. Hauswirth*

Name and Title

Judith W. Hauswirth, Ph.D.  
ChemReg International  
Authorized Agent for Sinon CorporationDate  
October 14,  
2003

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Applicant's/Registrant's Name and Address: Sinon Corp.  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

Product: Paraquat Technical Concentrate

Ingredient: paraquat dichloride

| Guideline Reference Number | Guideline Study Name                | MRID Number                                        | Submitter                                                           | Status | Note |
|----------------------------|-------------------------------------|----------------------------------------------------|---------------------------------------------------------------------|--------|------|
| 870.7600                   | Dermal penetration                  | 126096,<br>126097,<br>126098,<br>126099,<br>153439 | Scotts                                                              | Old    |      |
| 850.2100                   | Acute avian oral - quail/duck       | 29001, 102038,<br>160000,<br>5008363               | Scotts Co, Pesticon Systems, US F&WS,<br>Bayer Corp.                | Old    |      |
| 850.2200                   | Avian dietary - quail               | 22923                                              | US F&WS                                                             | Publ   |      |
| 850.2200                   | Avian dietary - duck                | 22923                                              | US F&WS                                                             | Publ   |      |
| 850.2300                   | Avian reproduction quail            | 110453,<br>110454                                  | Scotts Co.                                                          | Old    |      |
| 850.2300                   | Avian reproduction duck             | 110455                                             | Scotts Co.                                                          | Old    |      |
| 850.1075                   | Fish toxicity bluegill              | 40098001,<br>162737                                | Syngenta Whang<br>Gnt<br>US F&WS,<br>USEPA                          | Old    |      |
| 850.1075                   | Fish toxicity rainbow trout         | 40098001,<br>162736,<br>162738                     | Syngenta, Zeneca<br>Gnt<br>US F&WS, USEPA<br>Government, literature | Old    |      |
| 850.1010                   | Invertebrate toxicity               | 40098001,<br>114473,<br>GS262-028-2                | Syngenta, Zeneca                                                    | Old    | Fn I |
| 850.4225                   | Seed germination/seedling emergence | 42639601 0K                                        | Zeneca                                                              | Pay    |      |
| 850.4250                   | Vegetative vigor                    | 42601001 0K                                        | Zeneca                                                              | Pay    |      |

Signature: Judith W. Hauswirth

Name and Title: Judith W. Hauswirth, Ph.D.  
ChemReg International  
Authorized Agent for Sinon Corporation

Date: October 14, 2003





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| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 5 of 7                             |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          | Product: Paraquat Technical Concentrate |
| Ingredient: paraquat dichloride                                                                                                       |                          |                                         |

| Guideline Reference Number | Guideline Study Name                  | MRID Number                                                  | Submitter                       | Status  | Note         |
|----------------------------|---------------------------------------|--------------------------------------------------------------|---------------------------------|---------|--------------|
| 850.44(0)                  | Aquatic plant growth ✓                | 42601002,<br>42601003,<br>42601004,<br>42601005,<br>42601006 | Zeneca                          | Pay     |              |
| 850.30(2)                  | Honey bee acute contact ✓             | 5001991, ✓<br>28772, 111488                                  | Dow Chemical, unknown submitter | Old     |              |
| 875.22(0)                  | Soil residue dissipation              | Waived                                                       |                                 |         | Waived - RED |
| 875.24(0)                  | Dermal passive dosimetry exposure     | Waived                                                       |                                 |         | Waived - RED |
| 875.25(0)                  | Inhalation passive dosimetry exposure | Waived                                                       |                                 |         | Waived - RED |
| 161-1                      | Hydrolysis                            | Upton ✓                                                      |                                 | State 2 | Fin 2        |
| 161-2                      | Photodegradation - water              | 40562301 ✓                                                   | Zeneca                          | Old (?) | 2003 15/18   |
| 161-3                      | Photodegradation - soil               | Pack ✓                                                       |                                 |         | Fin 2        |
| 162-1                      | Aerobic soil metabolism               | 41319301 ✓                                                   | Zeneca                          | Pay     |              |
| 162-2                      | Anaerobic soil metabolism             | 41319302 ✓                                                   | Zeneca                          | Pay     |              |
| 163-1                      | Leaching/adsorption - desorption      | 40762701 ✓                                                   | Zeneca                          | Old     | 2003 15/18   |
| 164-1                      | Terrestrial field dissipation         | 41352101, ✓<br>41352102 ✓                                    | Zeneca                          | Pay     |              |
| 164-5                      | Long term soil dissipation ✓          | 42802101, ✓<br>42802102, ✓<br>42738701, ✓<br>42738702 ✓      | Zeneca                          | Pay     |              |
| 165-1                      | Confined rotational crop              | 41645601 ✓                                                   | Zeneca                          | Pay     |              |

|                                         |                                                                                                                 |                             |
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| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC | Product: Paraquat Technical Concentrate |             |
| Ingredient: paraquat dichloride                                                                                                       |                                         |             |

| Guideline Reference Number | Guideline Study Name                | MRID Number | Submitter                                | Status      | Note         |
|----------------------------|-------------------------------------|-------------|------------------------------------------|-------------|--------------|
| 165-5                      | Bioaccumulation - aquatic nontarget | Waived      |                                          |             | Waived - RED |
| 840.1100                   | Droplet size spectrum               | Cite-all    | Spray Drift Task Force                   | Pay         |              |
| 840.1200                   | Drift field evaluation              | Cite-all    | Spray Drift Task Force                   | Pay         |              |
| 860.1300                   | Nature of residue - plants          | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/pub |              |
| 860.1300                   | Nature of residue - livestock       | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/pub |              |
| 860.1340                   | Residue analytical methods          | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/pub |              |
| 860.1360                   | Multiresidue method                 | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/pub |              |
| 860.1380                   | Storage stability of residues       | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/pub |              |
| 860.1500                   | Crop field trials                   | Cite-all    | Zeneca, Scotts Co., IR-4, Shell Chemical | Pay/old/pub |              |
| 860.1520                   | Processed food/feed                 | Cite-all    | Zeneca                                   | Pay/old/pub |              |
| Special                    | Endangered Species                  | Cite-all    | Endangered Species Task Force            | Pay         |              |

NOTE: Guidelines listed but shown as "Not required" in RED, Appendix B are not included here as the guideline has been determined to be not applicable (1) as referenced in RED, Appendix B. C.

US EPA (1575) 48-hour EC50: Paraquat dichloride 29.1%. Daphnia magna: Test 2431. Unpublished report prepared by Terrestrial Aquatic Biology Laboratory. 1 p

|                                         |                                                                                                                 |                          |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14, 2003 |
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| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol                | Page 7 of 7 |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC | Product: Paraquat Technical Concentrate |             |
| Ingredient: paraquat dichloride                                                                                                       |                                         |             |

(2) as referenced in RED, Appendix B: "Guideline fulfilled; no MRID #'s for this study - review dated 2/14/85

(11)

|                                         |                                                                                                                 |                             |
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# Paraquat RED

## 2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into an \_\_\_\_\_ [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) \_\_\_\_\_ [fill blank only with those uses that are being supported by MP registrant]."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

"Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

- (a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."
- (b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

## B. End-Use Products

### 1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

### 2. Labeling Requirements for End-Use Products

**a. Application Rates and Label Deletions**

In cooperation with the Agency the registrant has agreed to the following application rates and label deletions:

- The maximum paraquat dichloride application rate for all products will be lowered from 1.6 lb cation/A to 1.0 lb cation/A.
  - For broadcast applications of paraquat with backpack sprayers, **non-spot**, the application rate should not exceed 0.625 lb cation/A and the application volume should be no less than 20 gallons per acre.
  - The maximum application rate for **spot spraying** on all paraquat labels will be no more than 0.0195 lbs cation/gallon.
- Delete the plastic acid bottle and the tree injection directions for use from the resin soaking sections of all paraquat dichloride labels.

**b. Hazard Statement**

The following hazard statement must be placed in the "Environmental Hazard" section of all paraquat labels to warn the user about possible adverse effects to non-target terrestrial and semi-aquatic plants due to drift:

"Paraquat dichloride is toxic to nontarget crops and plants if off-target movement occurs. Extreme care must be taken to ensure that off-target drift is minimized to the greatest extent possible."

**c. PPE/Engineering Control Requirements for Pesticide Handlers**

For **sole-active-ingredient** end-use products that contain paraquat, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain paraquat, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

**d. Products Intended Primarily for Occupational Use (WPS and nonWPS)**

**Minimum (Baseline) PPE/Engineering Control Requirements**

Although the MOE's were greater than 100 for all but two scenarios (backpack applicators and resin-soaking uses) without personal protective equipment requirements beyond long-sleeve shirt, long pants, shoes and socks, the Agency notes the relatively significant epidemiological evidence of poisonings from intentional/accidental swallowing and numerous non-systemic skin and eye effects in California (see OREB J. Blondell memo, 12/5/95). These considerations have led to the Agency establishing the following minimum (baseline) PPE for all occupational uses of paraquat end-use products:

"Mixers and loaders must wear:

- long-sleeved shirt and long pants,
- chemical-resistant gloves\*,
- shoes plus socks,
- chemical-resistant apron,
- face shield"

Although there is no direct evidence that occupational handlers have ever ingested a lethal amount of paraquat from a splash or spill, the requirement for a face shield for all mixers and loaders reflects the Agency's particular concern about accidental swallowing in case of a spill or splash back.

"Applicators and other handlers (other than mixers and loaders) must wear:

- long-sleeved shirt and long pants,
- chemical-resistant gloves\*,
- shoes plus socks"

\* For the glove statement, use the statement established for paraquat through the instructions in Supplement Three of PR Notice 93-7.

**Determining PPE Requirements for End-use Product Labels**

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

### **Placement in Labeling**

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

### **Products Intended Primarily for Occupational Use**

There are no registered homeowner-use products

#### **Entry Restrictions**

For **sole-active-ingredient** end-use products that contain paraquat the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain paraquat the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

#### **e. Products Intended Primarily for Occupational Use - Entry Restrictions and Labeling**

#### **WPS Uses**

##### **Restricted-entry interval:**

"For preplant or preemergence (broadcast or banded) applications, post-emergence directed-spray applications, dormant-season applications, and "between cutting" alfalfa applications: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."

"For harvest-aid and desiccation applications: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."

##### **Early-entry personal protective equipment (PPE):**

The PPE required for early entry is:

- coveralls,
- chemical-resistant gloves\*,
- shoes plus socks,

-- protective eyewear.

\* For the glove statement, use the statement established for paraquat through the instructions in Supplement Three of PR Notice 93-7:

**WPS Notification Statement:**

Not required on label.

**Placement in labeling:**

The REI statements must be inserted into the Agricultural Use Requirements box as required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7. The double notification statement must be placed into the Agricultural Use Requirements box as required by Supplement Three of PR Notice 93-7.

**NonWPS uses**

**Entry restrictions:**

The Agency is establishing the following entry restrictions for nonWPS occupational uses of paraquat end-use products:

"Do not enter or allow others to enter the treated area until sprays have dried."

**Placement in labeling:**

**If WPS uses are also on label** -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

**If no WPS uses are on the label** -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

**Products Intended Primarily for Homeowner Use**

**Entry restrictions:**

There are no registered homeowner-use products.

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#### **f. Other Labeling Requirements**

##### **Products Intended Primarily for Occupational Use**

The Agency is requiring the following labeling statements to be located on all end-use products containing paraquat that are intended primarily for occupational use.

##### **Application Restrictions**

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

##### **Engineering Controls**

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

##### **User Safety Requirements**

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable, use detergent and hot water. Keep and wash PPE separately from other laundry."

"DO NOT USE AROUND HOMES, SCHOOLS, RECREATIONAL PARKS, GOLF COURSES, OR PLAYGROUNDS"

##### **User Safety Recommendations**

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

### C. Spray Drift Labeling

The following language must be placed on each paraquat product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.
2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they shall be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

#### INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable

environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

### **CONTROLLING DROPLET SIZE**

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.
- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.
- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

### **BOOM LENGTH**

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

### **APPLICATION HEIGHT**

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

### **SWATH ADJUSTMENT**

When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.

Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

## **WIND**

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

## **TEMPERATURE AND HUMIDITY**

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

## **TEMPERATURE INVERSIONS**

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

## **SENSITIVE AREAS**

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

### **D. Existing Stocks**

## Use Groups and Sites:

### TERRESTRIAL FOOD CROP

acerola (West Indies cherry); apricot; asparagus; avocado; banana; blackberry; blueberry; boysenberry; broccoli; cabbage; cabbage, Chinese; carrot (including tops); cauliflower; cherry; cocoa; coffee; collards; cucumber; eggplant; fig; filbert (hazelnut); garlic; groundcherry (strawberry tomato/tomatillo); guava; hops; kiwifruit; lettuce; loquat; macadamia nut (bushnut); manioc (cassava); melons; melons, cantaloupe; melons, musk; melons, water; mint; nectarine; olive; onion; papaya; passion fruit; peach; pear; pecan; pepino (melonpear); pepper; pepper (chili type); pineapple; pistachio; plum; potato, white/Irish; prune; pumpkin; raspberry (black, red); rhubarb; smallfruits; squash (all or unspecified); strawberry; sugarbeet; taro; walnut (English/black); yam; yautia

### TERRESTRIAL FOOD+FEED CROP

almond; apple; barley; beans, asparagus; beans, dried-type; beans, mung; beans, succulent (lima); beans, succulent (snap); citrus fruits; corn (unspecified); corn, field; corn, pop; corn, sweet; cotton (unspecified); garbanzos (including chickpeas); grapes; guar; hops; legume vegetables; mint; oats; orchards (unspecified); peanuts; peanuts (unspecified); peas (unspecified); peas, field; peas, pigeon; peppermint; potato, white/Irish; safflower; safflower (unspecified); small fruits; small grains (unspecified); sorghum; sorghum (unspecified); soybeans (unspecified); soybeans, edible; spearmint; sugarbeet; sugar crops; sugarcane; sunflower; tomato; turnip; vegetables (unspecified); wheat

### TERRESTRIAL FEED CROP

alfalfa; barley; beans; clover; crownvetch; legume vegetables; lespedeza; lupine; pastures; sainfoin; timothy; trefoil; tyfon; vetch; wheat

### TERRESTRIAL NON-FOOD CROP

agricultural fallow/idleland; airports/landing fields; commercial/industrial lawns; commercial/institutional/industrial; premises/equipment (outdoor); fencerows/hedgerows; grasses grown for seed; industrial areas (outdoor); jojoba; nonagricultural outdoor buildings/structures; nonagricultural uncultivated areas/soils; ornamental and/or shade trees; peach (non-bearing, seed beds); recreation area lawns; tomato (post-harvest); wood protection treatment to forest products (seasoned)

### FORESTRY

forest plantings (reforestation programs); pine (forest/shelterbelt); shelterbelt plantings

## **TERRESTRIAL NON-FOOD**

ornamental and/or shade trees; ornamental herbaceous plants;  
ornamental woody shrubs and vines; non-crop areas such as public  
airports, electric transformer stations and around commercial buildings

**Target Pests:** Annual broadleaf and grassy weeds (top kill of  
perennials).

### **Formulation Types Registered:**

#### **MANUFACTURING PRODUCT**

Soluble concentrate/liquid 43.5000%

#### **END USE PRODUCT**

Soluble concentrate/liquid 23.2000 to 43.5000%  
(23.2000%, 29.1000%, 29.4200%,  
30.3000%, 37.000%, 43.5000%)

**Multiple active ingredient products contain:**  
diuron (035505)

### **Method and Rates of Application:**

#### **TYPES OF TREATMENT**

Band treatment; Bark treatment (cut); Basal spray treatment; Bore-hole  
treatment; Broadcast; Directed spray; Ground spray; Soil band  
treatment; Soil broadcast treatment; Spot soil treatment; Spot treatment;  
Spray; Strip treatment.

#### **EQUIPMENT**

Aircraft; Backpack/Knapsack sprayer; Hand held spray wand; Sprayer;  
Ground/Tractor-drawn ground boom.

#### **TIMING**

At cracking; At planting; August; Dormant; Early spring; Established  
plantings; Fall; Fallow; Foliar; July; Postemergence; Postharvest;  
Postplant; Posttransplant; Preemergence; Preharvest; Preplant; Preplant  
(Spring); Ratoon; Seed bed; Seedling stage; Spring; Stubble; When  
needed; Winter.

### **C. Estimated Usage of Pesticide**

This section summarizes the best estimates available for the pesticide uses of  
paraquat dichloride. These estimates are derived from a variety of published and  
proprietary sources available to the Agency. The data, reported on an aggregate and  
site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in  
using data from various information sources.

## PARAQUAT Concentrate ES

For Formulation of Paraquat Herbicide Products Only

Refer to Syngenta Manufacturing Formulas for Formulating Directions, Chemical and Physical Properties

### ACTIVE INGREDIENT:

Paraquat dichloride (1,1'-dimethyl-4,4'-bipyridinium dichloride)..... 45.6%

**INERT INGREDIENTS:**..... 54.4%

**TOTAL** ..... 100.0%

Contains 3.14 pounds paraquat cation per gallon as 4.332 pounds salt per gallon.

Contains emetic.

**KEEP OUT OF REACH OF CHILDREN**



**DANGER/ POISON**  
**PELIGRO**

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS.
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN STATEMENT OF PRACTICAL TREATMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

See additional precautionary statements and directions for use (inside booklet; on back panel; on side panel)

EPA Reg No. 100-1067

EPA Est No. xxxx

Product of USA

SCP xxxx

Net Weight/U.S. Standard Measure

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

SEP 16 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

100-1067

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Contains Paraquat, a Bipyridylium Herbicide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                          |
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <ul style="list-style-type: none"><li>•SPEED IS ESSENTIAL. Immediate medical attention is required. If available, give an adsorbent such as activated charcoal, bentonite or Fullers Earth.</li><li>•Call a poison control center or doctor immediately for treatment advice.</li><li>•Do not give anything by mouth to an unconscious person.</li></ul> |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"><li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>•Call a poison control center or doctor for treatment advice.</li></ul>                                                         |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <ul style="list-style-type: none"><li>•Take off contaminated clothing.</li><li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>•Call a poison control center or doctor for treatment advice.</li></ul>                                                                                                                           |
| If inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"><li>•Move person to fresh air.</li><li>•The odor of this product is from the stenching agent, which has been added, not from the paraquat.</li><li>•If person is not breathing, call 911 or an ambulance.</li><li>•Call a poison control center or doctor for further treatment advice.</li></ul>                      |
| <b>NOTE TO PHYSICIAN</b><br><br>Refer to the booklet 'Paraquat Poisoning. A Practical Guide to Diagnosis, First Aid and Hospital Treatment'. ( <a href="http://www.syngenta.com/pqmedguide/">http://www.syngenta.com/pqmedguide/</a> ) Administer either activated charcoal (100g for adults or 2g/kg body weight in children) or Fuller's Earth (15% solution; 1 liter for adults or 15ml/kg body weight in children). NOTE: The use of gastric lavage without administration of an adsorbent has not shown any clinical benefit. Do not use supplemental oxygen. Eye splashes from concentrated material should be treated by an eye specialist after initial treatment. With the possibility of late onset corneal ulceration, it is advised that patients with paraquat eye injuries are reviewed by an eye specialist the day after first presentation. Use treatment that is appropriate for chemical burns. Intact skin is an effective barrier to paraquat, however contact with irritated or cut skin or repeated contact with intact skin may result in poisoning. |                                                                                                                                                                                                                                                                                                                                                          |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment..                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                          |



**HOT LINE NUMBER**

For 24-Hour Medical Emergency Assistance (Human or Animal)  
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)  
Call  
**1-800-888-8372**

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**



**DANGER/ POISON  
PELIGRO**

May be fatal if swallowed. Fatal if inhaled. Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe spray mist. Do not inhale contaminated plant dust.

**IMPORTANT:** Inhalation is an unlikely route of exposure due to low vapor pressure, but mucosal irritation or nose bleeds may occur. Prolonged contact with this concentrated product can irritate your skin.

When handling or mixing concentrate or when exposure to concentrate is possible, wear:

- Long-sleeve shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Face shield
- Protective eyewear

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.  
**REMOVE** contaminated clothing and wash separate from other laundry before reuse.

**ENVIRONMENTAL HAZARDS**

**WILDLIFE:** This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

**PHYSICAL AND CHEMICAL HAZARDS:** This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

### **SPILLAGE DURING TRANSPORT**

**Emergency action:** Notify police and fire departments immediately. For any spill, leak, fire or exposure in the United States, call 1-800-888-8372. In other countries, call your local Syngenta agent.

KEEP PUBLIC AND ANIMALS away from area. MARK ROADS AND WARN OTHER ROAD USERS. WEAR face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to insure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water if feasible.

## **CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Syngenta Crop Protection, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Syngenta and Seller harmless for any claims relating to such factors.

Syngenta warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Syngenta, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall Syngenta or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Syngenta and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Syngenta.

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## **DIRECTIONS FOR USE**

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It is a violation of Federal law to use this product without complying with all label directions and warnings.

**READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.**

Only for formulation into an herbicide for the following uses:

- (1) Terrestrial Food: Alfalfa, Almonds, Asparagus, Cassavas, Clover and other Legumes, Corn (pop, field, sweet, and seed), Cotton, Dry beans, Easter Lilies, Fallow land, Garlic, Guar, Guava, Hops, Lentils, Mint, Onions, Passion Fruit, Pastures, Peanuts, Pigeon peas, Pineapple, Potato, Rice, Safflower, Small fruits, Small grains, Sorghum, Soybeans, Sugar Beets, Sugarcane, Sunflower, Taniers, Taro, Trees and Vines, Tyfon, Vegetables, Yams;

Terrestrial Nonfood: Conservation Compliance Lands, Conservation Reserve Lands, Federal Set-Aside Lands, Grasses grown for seed, Resin soaking (pines), Tree Plantation Establishment;

- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

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## **STORAGE AND DISPOSAL**

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**PESTICIDE STORAGE:** Do not contaminate water, food, or feed by storage or disposal. Store at temperatures above 32°F. For help with any spill, leak, or fire involving this material, call **1-800-888-8372**.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**RECYCLABLE/REFILLABLE CONTAINERS:** Before refilling, inspect thoroughly for damage, such as cracks, punctures, bulges, dents, abrasions and damaged or worn

threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.

**CONTAINER IS NOT SAFE FOR FOOD, FEED OR DRINKING WATER!**

© xxxx Syngenta

For non-emergency (e.g., current product information) call  
Syngenta Crop Protection at 1-800-334-9481

Syngenta Crop Protection, Inc.  
Greensboro, North Carolina 27409  
[www.syngenta-us.com](http://www.syngenta-us.com)

SCP XXX

PARAQUAT CONCENTRATE ES 1067 FIRSTAID CLEAN – pd 08-26-03  
000100-01067.20030902.PARAQUAT.CONCENTRATE.ES.1067.FIRSTAID.pdf

*Restricted Use?*

*Restricted Use*

## Paraquat Technical Concentrate

For Formulation of Paraquat Herbicide Products Only

### ACTIVE INGREDIENT

Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride).....46.2%

INERT INGREDIENTS.....53.8%

TOTAL.....100.0%

Contains 3 pounds paraquat cation per gallon

*Contains emetic*  
EPA Reg. No. 70552-x

EPA Establishment No. 70552-TWN-001

**KEEP OUT OF REACH OF CHILDREN  
DANGER - PELIGRO**



**POISON**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS.
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

### *SPEED IS ESSENTIAL* FIRST AID

|                        |                                                                                                                                                                                                                                                                                                                                             |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed           | <ul style="list-style-type: none"><li>• Call Poison Control Center or doctor immediately for treatment advice</li><li>• Have person sip a glass of water if able to swallow</li><li>• Do not induce vomiting unless told to by a poison control center or doctor</li><li>• Do not give anything by mouth to an unconscious person</li></ul> |
| If inhaled             | <ul style="list-style-type: none"><li>• Move person to fresh air</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                         |
| If in eyes             | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                            |
| If on skin or clothing | <ul style="list-style-type: none"><li>• Take off contaminated clothing</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                                                                                 |

### HOTLINE

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.

### NOTE TO PHYSICIANS

CALL CHEMTREC 1-800-424-9300 at any hour to obtain toxicology and medical management consultation and paraquat analyses. Prompt treatment is essential and must be initiated immediately before signs and symptoms appear. Symptoms are prolonged and painful and may be delayed for days after swallowing. Treatment may include binding paraquat in the gut with suspensions of clay or charcoal; and/or removal of paraquat from the blood by prolonged charcoal hemoperfusion or continuous hemodialysis. Probable mucosal damage may contraindicate the use of gastric lavage.

*Do not use supplemental oxygen.*

*Not same as synergists.*

*(130)*

*needs to address  
inhalation category I*

PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER - POISON



Fatal if inhaled. May be fatal if swallowed. ~~Causes substantial but temporary eye injury.~~ Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe spray mist. Do not inhale contaminated dust. ~~Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.~~

- #2 add wear "Respiratory protection"
- When handling or mixing concentrate or when exposure to concentrate is possible, wear:

- ~~Dust/mist filtering NIOSH approved respirator with any R, P or HE filter~~ keep.
- ~~Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)~~ keep.
- Full face shield
- Chemical-resistant gloves, Category-A shoes + socks

Chem-resistant Apron and waterproof footwear ~~Chemical resistant~~

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

IMPORTANT: The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

ENVIRONMENTAL HAZARDS

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

PHYSICAL AND CHEMICAL HAZARD

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

EQUIPMENT/CONTAINER: Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

SPILLAGE DURING TRANSPORT

Emergency Action: Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

KEEP PUBLIC AND ANIMALS away from area. MARK ROADS AND WARN OTHER ROAD USERS.

WEAR face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into a herbicide for the following uses:

- (1) Terrestrial Food: ~~Alfalfa~~, ~~Almond~~, ~~Asparagus~~, ~~Beans Dry~~ (Adzuki beans, Asparagus bean, Black bean, Broad bean, Field bean, Garbanzo bean, White sweet lupine, White lupine, Kidney bean, Lablab bean, Lima bean, Fava bean, Mung bean, Navy bean, Pinto bean, Rice bean, Snap bean, Tepary bean, Urd bean, Waxbean, Blackeyed pea, Chickpea, Cowpea, Crowder pea, Southern pea, Catjang, Guar), ~~Berries~~ (Blackberries, Blueberries, Boysenberries, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry), ~~Cassavas~~, ~~Clover~~, ~~Legumes~~ (Venvet bean, Lespedeza, Lupine, Sainfoin, Trefoil, Vetch, Crown Vetch, Milk Vetch), ~~Corn~~ (Pop, Field, and Sweet), ~~Cotton~~, ~~Grain lupine~~, ~~Grasses~~ (pasture and range), ~~Guava~~, ~~Hops~~, ~~Lentil~~, ~~Mint~~ (Peppermint, Spearmint), ~~Onions~~, ~~Garlic~~, ~~Passion fruit~~, ~~Pastures~~, ~~Peanuts~~, ~~Pigeon Peas~~, ~~Pineapple~~, ~~Potato~~, ~~Rice~~, ~~Safflower~~, ~~Small fruits~~, ~~Small grains~~ (Barley, Wheat), ~~Soybean~~ (grain), ~~Strawberries~~, ~~Soybeans~~, ~~Sugar beets~~, ~~Sugarcane~~, ~~Sunflower~~, ~~Sweet lupine~~, ~~Tanier~~, ~~Trees and Vines~~ (Acerola, Apple, Apricot, Avocado, Banana, Beechnut, Brazil nut, Butternut, Cashew, Cherry, Chestnut, Chinquapin, Citrus Citron, Coffee, Crabapple, Fig, Filbert, Grape, Grapefruit, Hickory nut, Kiwi fruit, Junquat, Lemon, Lime, Loquat, Macadamia nut, Mandarin, Mayhaw, Nectarines, Olive, Orange (sweet and sour), Papaya, Peach, Pear (oriental), Pecan, Pistachio, Plum, Prune, Pummelo, Quince, Satsuma mandarin, Walnut, Shade and Ornamental trees (such as Arbovitae, Ash, Elm, Oak, Pine, etc.)), ~~Tylan~~, ~~Vegetables~~ (Broccoli, Brussels sprouts, Cabbage, Cantaloupe, Carrot, Cauliflower, Cavalo, Chayote fruit, Chinese cabbage, Chinese wasgourd, Citron melon, Collard, Cucumber, Eggplant, Gherkin, Gourd (edible), Ground cherry, ~~Momordica~~ spp., Kale, Kohlrabi, Lettuce, Mizune, Musk melon, Mustard greens, Mustard spinach, Peas, Pepino, Pepper, Pumpkin, Rape greens, Squash, Sweet corn, Tomatillo, Tomato, Turnip, Watermelon, Eggplant, Pepper, Chili pepper, Rubarb), ~~Yams~~.

Terrestrial Nonfood: Conservation Compliance Lands, Conservation Reserve Lands, Federal Set-Aside Lands, Grasses grown for seed, resin soaking (pines), Tree plantation establishment.

- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

change  
crop  
designations  
to  
RED

or Tyfon

change  
to  
RED  
pg 3  
listings

or

Commodity  
listing  
on  
page  
103-107



#### WARRANTY STATEMENT

SINON CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by Buyer and User. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this product. SINON CORP. makes no warranties of merchantability or of fitness for a particular purpose nor for any other expressed or implied warranty except as stated above.

Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 10-14-2003. NOT EPA APPROVED

12/08/2004

Upon review of Shyam's memo dated December 6, 2004 concerning the product chemistry resubmission review, I noticed that 830.1670 had not been detailed (unacceptable from the 1<sup>st</sup> memo from Debra Rate dated July 1, 2004). I had Shyam take another look at the study submitted, and he determined that 830.1670 was acceptable. Therefore, all Product Chemistry requirements have been satisfied, except for corrosion characteristics and one year storage stability, currently in house, and will be considered conditions of registration.

Hope Johnson, RD/HB

DATE: 06/DEC/2004

SUBJECT:    **PRODUCT CHEMISTRY REVIEW OF TGA/MP [X] EP []**  
              **DP BARCODE No.: D306499 REG. No.: 70552-R**  
              **PRODUCT NAME: Paraquat Technical Concentrate**  
              **COMPANY: Sinon Corporation**  
              **PCC: 061601; Decision No.: 339337; FOOD USE [X]**  
              **INTEGRATED FORMULATION: Yes [X] NO []**

FROM:       Shyam B. Mathur,  
              Product Chemistry Team Leader  
              Technical Review Branch/RD (7505C)

TO:          Hope Johnson / James Tompkins, RM 25  
              Herbicide Branch/RD(7505C)

*Signature*  
*12/6/04*  
*DM*

#### INTRODUCTION

The product chemistry data for Paraquat technical concentrate was reviewed previously (see PCR dated July 1, 2004; D299077). In a Agency's letter of July 8, 2004, the registrant was informed of several deficiencies in the product chemistry data. The deficiencies pertained principally to 830 series Subgroup A. The registrant responded on July 31, 2004 and submitted the required data under MRID No. 463312-01 as a supplemental report to previous data with MRID No. 460988-01. The TRB has been asked to evaluate the supplemental report submitted.

#### SUMMARY OF FINDINGS

1. The Paraquat technical concentrate has the product label claim of 46.2%.
2. 830.1550 (product identity & composition): a revised CSF for basic formulation (dated 07-28-04) was submitted as per recommendation of the Agency. The CSF is filled out correctly & completely. The nominal concentration of the active ingredient concurs with the product label claim of 46.2% in compliance with PR Notice 91-2. The data submitted satisfy the data requirements of 40CFR§158.155.
3. 830.1620 (description of production process): additional information have been provided on the integrated production process. The additional information included the information on the reactors & equipments, the amounts of starting materials used and the reaction conditions and the flow diagram of the manufacturing process. The registrant has also described the quality control process which resulted in the consistence purity of the AI in different batches. The data submitted satisfy the data requirements of 40CFR§158.162.
4. 830.1750 (certified limits): the registrant has provided the explanation for the proposed expanded certified limits for one of the inert ingredients. According to the registrant the proposed certified limits are based on the consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures were used and allow for all sources of variability likely to be encountered in the production process. The amount of the solvent in the final product may be adjusted to ensure that the active ingredient assay is within the proposed limits. The data submitted satisfy the data requirements of 40CFR§158.175.

DP BARCODE No.: D306499 REG. No.: 70552-R PRODUCT NAME: Paraquat Technical Concentrate

### CONCLUSIONS

The TRB has reviewed the supplemental data submitted for 830 series Subgroup A and has concluded that:

1. The product chemistry data submitted corresponding to guideline 830.1550 (product identity & composition) satisfy the data requirements of 40CFR§158.155. The revised CSF for basic formulation dated July 28, 2004 is acceptable.

2. The data submitted corresponding to guideline 830.1620 (description of production process) satisfy the data requirements of 40CFR§158.162 and are acceptable.

3. The data submitted corresponding to guideline 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.175 and are acceptable. The justifications provided for expanded certified limits in case of one of the inert ingredient are acceptable.

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Registration File NO. 70552-1

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Page \_\_\_\_\_ is not included in this copy.

Pages 137 through 138 are not included in this copy.

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The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
  - ☐ Identity of product impurities.
  - ☒ Description of the product manufacturing process.
  - ☐ Description of quality control procedures.
  - ☐ Identity of the source of product ingredients.
  - ☐ Sales or other commercial/financial information.
  - ☐ A draft product label.
  - ☐ The product confidential statement of formula.
  - ☐ Information about a pending registration action.
  - ☐ FIFRA registration data.
  - ☐ The document is a duplicate of page(s) \_\_\_\_\_.
  - ☐ The document is not responsive to the request.
- 

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

AUG 15 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Dr. Elizabeth A. Brown  
ChemReg International, LLC  
Consultant for: Sinon Corporation  
1990 Old Bridge Rd, Suite 201  
Lake Ridge, VA 22192-2383

Dear Dr. Brown:

Subject: Paraquat Technical Concentrate  
EPA Registration Number 70552-R

~~Product Chemistry Review~~

*Acute Toxicology*

The acute toxicity 6-pack studies, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, has been found to meet the data requirements as specified in 40 CFR 158.340 (a).

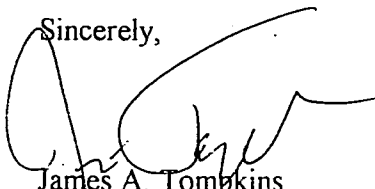
Please note the following comments from the Technical Review Branch:

1. The incorrect protocol (OECD 401: Acute Oral LD50) was used for this test. Although we accepted the study in this case, our guidance is that OECD 401 is an unacceptable protocol. Please note that the preferred protocol is OECD 425: Acute Oral Toxicity Up-and-Down procedure.
2. Although the acute inhalation toxicity study is unacceptable according to OECD guidelines, TRB does not require the test to be repeated due to the toxicity of the test substance. Paraquat Technical Concentrate is classified as toxicity category I for the inhalation route.

Please see the attached memo from the Technical Review branch for details.

If you have any questions, please contact Hope Johnson at 703-305-5410.

Sincerely,



James A. Tompkins  
Product Manager 25  
Herbicide Branch  
Registration Division (7505C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 28, 2004

MEMORANDUM

Subject: Name of Pesticide Product: Paraquat Technical Concentrate  
EPA File Symbol: 70552-R  
DP Barcode: D299079  
Decision No.: 339337  
PC Code: 061601

From: Breann Hanson, Toxicologist *BH*  
Technical Review Branch  
Registration Division (7505C) *SR*

To: Hope Johnson, RM Team 25  
Herbicide Branch  
Registration Division (7505C)

Applicant: Sinon Corporation  
.111, Chuang-Shan Road  
Ta-Tu Hsiang, Tacichung Hsien 432  
Taiwan, ROC

FORMULATION FROM LABEL:

| <u>Active Ingredient:</u>                    | <u>% by wt.</u> |
|----------------------------------------------|-----------------|
| 061601 Paraquat dichloride CAS No. 1910-42-5 | 46.2%           |
| <u>Inert Ingredients:</u>                    | <u>53.8 %</u>   |
| Total:                                       | 100.00%         |

## ACTION REQUESTED:

The Product Manager requests:

"The registrant, Sinon Corporation, has applied for a me-too registration with REG. No. 100-1067. They have included the 6-pack tox studies, which i am forwarding to you, along with the proposed CSF, label, me-too label, me-too CSFs (including numerous alternate formulations), and the label for 1812-424, a cancelled product they cite in their letter. Please note that they have not submitted an acute oral toxicity study, but instead have cited this study on their data matrix with the MRID 43685001. I am also forwarding you the letter, form and data matrix. Please review the studies for acceptance, and determine if the proposed product is substantially similar to 100-1067..."

**BACKGROUND:** Sinon Corporation has submitted a six pack of acute toxicity studies (5 submitted, one cited on their data matrix) in support of registration for Paraquat Technical Concentrate, EPA File Symbol 70552-R. The submission included a CSF, letter, label for the proposed product and me-too label and CSF. Although the letter states that the product is similar to 100-1067, because studies were submitted no comparison was required with the proposed product. The studies were conducted at Zeneca Central Toxicology Laboratory, Chesire, UK and Inveresk Research, Tranent, Scotland, with assigned MRID numbers 436850-01 and 460988-03 through -07. The active ingredient is not yet registered with the EPA.

**RECOMMENDATIONS:** The six studies have been reviewed and 5 are classified as acceptable. Although the acute inhalation toxicity study is unacceptable according to OECD guidelines, TRB does not require the test to be repeated due to the toxicity of the test substance. Paraquat Technical Concentrate is classified as toxicity category I for the inhalation route. The acute toxicity profile for Paraquat Technical Concentrate, EPA File Symbol 70552-R is:

|                           |          |              |                            |
|---------------------------|----------|--------------|----------------------------|
| Acute oral toxicity       | II       | Acceptable   | MRID 43685001 <sup>a</sup> |
| Acute dermal toxicity     | III      | Acceptable   | MRID 46098803              |
| Acute inhalation toxicity | I        | Unacceptable | MRID 46098804              |
| Primary eye irritation    | I        | Acceptable   | MRID 46098805              |
| Primary skin irritation   | IV       | Acceptable   | MRID 46098806              |
| Dermal sensitization      | Negative | Acceptable   | MRID 46098807              |

<sup>a</sup> The incorrect protocol (OECD 401: Acute Oral LD50) was used for this test. Although, we accepted the study in this case, our guidance is that OECD 401 is an unacceptable protocol. Please inform the Registrant that the preferred protocol is OECD 425: Acute Oral Toxicity-Up-and-Down Procedure.



**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

**PRODUCT ID #:** 070552-00001

**PRODUCT NAME:** Paraquat Technical Concentrate

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals:**

**SIGNAL WORD:** DANGER  
POISON ☒

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Fatal if inhaled. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Do not breathe spray mist. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

**First Aid:**

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**Note to PM/CRM/Registrant:**

The proposed label should contain a Note to Physician which addresses the category I Acute Inhalation Toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Also, on the proposed label the registrant is claiming a toxicity category II classification for eye irritation, ie. "Causes substantial but temporary eye injury." Due to the toxicity category of I for eye irritation, this must be changed to read "Causes irreversible eye damage."



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

|                                                                                                                                                                                                                 |                                                                                                                                                                                                                        |                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| 1. Company/Product Number<br>70552-R                                                                                                                                                                            | 2. EPA Product Manager<br>Jim Tompkins                                                                                                                                                                                 | 3. Proposed Classification<br><input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Paraquat Technical Concentrate                                                                                                                                                     | PM #<br>25                                                                                                                                                                                                             |                                                                                                            |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Sinon Corporation<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC<br><input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:<br>EPA Reg No. <u>100-1067</u><br>Product Name <u>Paraquat Concentrate ES</u> |                                                                                                            |

## Section - II

|                                                                                                     |                                                                                  |
|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| <input type="checkbox"/> Amendment - Explain below                                                  | <input type="checkbox"/> Final printed labels in response to Agency letter dated |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>7/8/2004</u> | <input checked="" type="checkbox"/> "Me Too" Application                         |
| <input type="checkbox"/> Notification - Explain below                                               | <input type="checkbox"/> Other - Explain below                                   |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Response to Agency letter of July 8, 2004

## Section III

|                                                                                                                         |                                                                                          |                                                                                                                              |                   |                                                                                                                                           |                                                |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| 1. Material This Product Will be Packaged in:                                                                           |                                                                                          |                                                                                                                              |                   | 2. Type of Container                                                                                                                      |                                                |
| Child-Resistant Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No                     | Unit Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No                            |                   | <input type="checkbox"/> Metal                                                                                                            | <input checked="" type="checkbox"/> Plastic    |
| *Certification must be submitted                                                                                        |                                                                                          | If "Yes" Unit Packaging wgt.                                                                                                 | No. per container | If "Yes" Package wgt.                                                                                                                     | No. per container                              |
|                                                                                                                         |                                                                                          |                                                                                                                              |                   |                                                                                                                                           | <input type="checkbox"/> Glass                 |
|                                                                                                                         |                                                                                          |                                                                                                                              |                   |                                                                                                                                           | <input type="checkbox"/> Paper                 |
|                                                                                                                         |                                                                                          |                                                                                                                              |                   |                                                                                                                                           | <input type="checkbox"/> Other (Specify) _____ |
| 3. Location of Net Contents Information<br><input checked="" type="checkbox"/> Label <input type="checkbox"/> Container |                                                                                          | 4. Size(s) Retail Container<br>60 gallon HDPE                                                                                |                   | 5. Location of label directions<br><input checked="" type="checkbox"/> On Label<br><input type="checkbox"/> On Label accompanying product |                                                |
| 6. Manner in Which Label is Affixed to Product                                                                          |                                                                                          | <input type="checkbox"/> Lithograph<br><input checked="" type="checkbox"/> Paper glued<br><input type="checkbox"/> Stenciled |                   | <input type="checkbox"/> Other _____                                                                                                      |                                                |

## Section IV

|                                                                                                                                                                                                                                                                               |  |                                                             |  |                                                   |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-------------------------------------------------------------|--|---------------------------------------------------|-----------------------------------------------|
| 1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)                                                                                                                                |  |                                                             |  |                                                   |                                               |
| Name<br>Elizabeth Anne Brown                                                                                                                                                                                                                                                  |  | Title<br>Authorized Agent,<br>ChemReg International, LLC    |  | Telephone No. (Include Area Code)<br>703-492-7905 |                                               |
| Certification<br>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.<br>I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law |  |                                                             |  |                                                   | 6. Date Application Received<br><br>(Stamped) |
| 2. Signature<br><i>Elizabeth Anne Brown</i>                                                                                                                                                                                                                                   |  | 3. Title<br>Authorized Agent,<br>ChemReg International, LLC |  |                                                   |                                               |
| 4. Typed Name<br>Elizabeth Anne Brown                                                                                                                                                                                                                                         |  | 5. Date<br>7/31/2004                                        |  |                                                   |                                               |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 2, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

SINON USA  
SINON CORP  
1080 CAROL LANE, SUITE 264  
LAFAYETTE, CA 94549-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 30-JUL-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

S: 764987

Print Letter

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Enter More Information

Application Type: Miscellaneous Receipt

Fee For Service: ☐ Yes ☒ No

Company: 70552 SINON CORP. ☒

Risk Manager: Registration Division: Risk Management Team 25

Product #: 70552-R Product Name: PARAQUAT-TECHNICAL CONCENTRATE

Override#:

Me Too Section 3: Me Too Product Name:

Application Date: 30-Jul-2004 ☒

OPP Rec'd Date: 30-Jul-2004 ☒

Receipt Content:  
Study

Front End Date: 02-Aug-2004 ☒

Risk Manager Send Date: 02-Aug-2004 ☒

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

supplement to MRID 46098801

New Ingredient Request Date:  
New Ingredient Received Date:  
Signature Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

July 31, 2004

Document Processing Desk  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

Attn: Jim Tompkins (PM 25)

Re: Paraquat Technical Concentrate (EPA File Symbol 70552-R)  
Response to Agency Letter of July 8, 2004

Dear Jim:

On behalf of our client, Sinon Corporation, enclosed please find information to respond to the questions and deficiencies raised in the Agency letter of July 8, 2004 with the enclosed review under DP Barcode 299077 for the above application for registration.

Sinon Corporation will accept submission of the one-year storage stability study (OPPTS 830.6317) and corrosion characteristics (OPPTS 830.6320) as a condition of registration and requests that adequate time for completion and submission of the report be allowed as a condition of registration.

Enclosed please find:

1. EPA Form 8570-1
2. Transmittal bibliography
3. Confidential Statement of Formula, EPA Form 8570-4
4. Three (3) copies of each submitted study

With this submission, we believe we have addressed all the Agency's concerns. Please contact me immediately if there are any questions or if anything else is needed.

Sincerely,

*Elizabeth Anne Brown*

Elizabeth Anne Brown

cc: Sinon Corporation

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CONSULTANTS TO SUCCESS<sup>SM</sup>

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# TRANSMITTAL DOCUMENT

## Submitter

Sinon Corporation  
111, Chung-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

## Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")  
(Paraquat Technical Concentrate 70552-R)

## Transmittal Date

July 31, 2004

## Submitted Studies

|             | MRID            |                                                                                                                                                                                                                              |
|-------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ----        |                 | Administrative Materials                                                                                                                                                                                                     |
| Document 1: | <b>46331201</b> | Brown, E.A. July 30, 2004. Supplemental Report to MRID 46098801: Paraquat Technical. Product Identity, Composition, and Analysis (Group A). ChemReg International, LLC. 14 pages. Contains Business Confidential Information |

Company Official

*Elizabeth Anne Brown*

Company Name: ChemReg International, LLC., Authorized Agent for Sinon Corporation

Company Contact: Elizabeth Anne Brown

Phone Number: 703-492-7905



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 28, 2004

MEMORANDUM

Subject: Name of Pesticide Product: Paraquat Technical Concentrate  
EPA File Symbol: 70552-R  
DP Barcode: D299079  
Decision No.: 339337  
PC Code: 061601

From: Breann Hanson, Toxicologist *BH*  
Technical Review Branch  
Registration Division (7505C) *SIN*

To: Hope Johnson, RM Team 25  
Herbicide Branch  
Registration Division (7505C)

Applicant: Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Tacichung Hsien 432  
Taiwan, ROC

FORMULATION FROM LABEL:

| <u>Active Ingredient:</u>                    | <u>% by wt.</u> |
|----------------------------------------------|-----------------|
| 061601 Paraquat dichloride CAS No. 1910-42-5 | 46.2%           |
| <u>Inert Ingredients:</u>                    | <u>53.8 %</u>   |
| Total:                                       | 100.00%         |



## ACTION REQUESTED:

The Product Manager requests:

"The registrant, Sinon Corporation, has applied for a me-too registration with REG. No. 100-1067. They have included the 6-pack tox studies, which i am forwarding to you, along with the proposed CSF, label, me-too label, me-too CSFs (including numerous alternate formulations), and the label for 1812-424, a cancelled product they cite in their letter. Please note that they have not submitted an acute oral toxicity study, but instead have cited this study on their data matrix with the MRID 43685001. I am also forwarding you the letter, form and data matrix. Please review the studies for acceptance, and determine if the proposed product is substantially similar to 100-1067..."

**BACKGROUND:** Sinon Corporation has submitted a six pack of acute toxicity studies (5 submitted, one cited on their data matrix) in support of registration for Paraquat Technical Concentrate, EPA File Symbol 70552-R. The submission included a CSF, letter, label for the proposed product and me-too label and CSF. Although the letter states that the product is similar to 100-1067, because studies were submitted no comparison was required with the proposed product. The studies were conducted at Zeneca Central Toxicology Laboratory, Chesire, UK and Inveresk Research, Tranent, Scotland, with assigned MRID numbers 436850-01 and 460988-03 through -07. The active ingredient is not yet registered with the EPA.

**RECOMMENDATIONS:** The six studies have been reviewed and 5 are classified as acceptable. **Although the acute inhalation toxicity study is unacceptable according to OECD guidelines, TRB does not require the test to be repeated due to the toxicity of the test substance.** Paraquat Technical Concentrate is classified as toxicity category I for the inhalation route. The acute toxicity profile for Paraquat Technical Concentrate, EPA File Symbol 70552-R is:

|                           |          |              |                            |
|---------------------------|----------|--------------|----------------------------|
| Acute oral toxicity       | II       | Acceptable   | MRID 43685001 <sup>a</sup> |
| Acute dermal toxicity     | III      | Acceptable   | MRID 46098803              |
| Acute inhalation toxicity | I        | Unacceptable | MRID 46098804              |
| Primary eye irritation    | I        | Acceptable   | MRID 46098805              |
| Primary skin irritation   | IV       | Acceptable   | MRID 46098806              |
| Dermal sensitization      | Negative | Acceptable   | MRID 46098807              |

<sup>a</sup> The incorrect protocol (OECD 401: Acute Oral LD50) was used for this test. Although, we accepted the study in this case, our guidance is that OECD 401 is an unacceptable protocol. Please inform the Registrant that the preferred protocol is OECD 425: Acute Oral Toxicity-Up-and-Down Procedure.

**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

**PRODUCT ID #:** 070552-00001

**PRODUCT NAME:** Paraquat Technical Concentrate

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals:**

**SIGNAL WORD:** DANGER  
POISON ☠

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Fatal if inhaled. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Do not breathe spray mist. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

**First Aid:**

**If inhaled:**

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

**If in eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison-control center or doctor for treatment advice.

**If swallowed:**

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

**If on skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**Note to PM/CRM/Registrant:**

The proposed label should contain a Note to Physician which addresses the category I Acute Inhalation Toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Also, on the proposed label the registrant is claiming a toxicity category II classification for eye irritation, ie. "Causes substantial but temporary eye injury." Due to the toxicity category of I for eye irritation, this must be changed to read "Causes irreversible eye damage."

Reviewer: Breann Hanson  
Risk Manager (EPA): Hope Johnson, RM 25

Date: July 28, 2004

**STUDY TYPE:** Acute Oral Toxicity - S-D rat; OPPTS 870.1100; OECD 401

**TEST MATERIAL:** Paraquat Dichloride Technical Concentrate (Paraquat: 33.0%; batch reference: F42; brown/black liquid)

**CITATION:** Duerden, L. (1994) Paraquat Dichloride Technical Concentrate: Acute Oral Toxicity to the Rat. Report No.: CTL/P/4424. Unpublished study prepared by Zeneca Central Toxicology Laboratory. September 30, 1995. MRID 43685001.

**SPONSOR:** Sinon Corporation, 111, Chuang-Shan Road, Ta-Tu Hsiang, Tacichung Hsien 432 Taiwan, ROC

**EXECUTIVE SUMMARY:** In an acute oral toxicity study (MRID 43685001), 20 male and 15 female young adult Wistar-derived albino rats (Weight: 244-286 g males, 167-202 g females; Source: Barriered Animal Breeding Unit, Cheshire, UK) were given a single oral dose of Paraquat Dichloride Technical Concentrate (Paraquat: 33.0%; batch reference: F42; brown/black liquid) by oral gavage at either 250, 100, 400 or 600 mg/kg (5/sex/group). The study was initially performed at a limit dose of 250 mg/kg based on a preliminary range study. The test substance was prepared in deionized water before administration. Individual animal body weights were recorded prior to test substance administration and for the surviving animals at intervals throughout the test period. Clinical checks for toxicity were made three times post-dosing on the initial study day, and at least daily thereafter for 14 days. All surviving animals were necropsied on study day 15. Oral LD<sub>50</sub> was calculated by logistic regression using nominal dose values.

Oral LD<sub>50</sub> Males = 344 mg/kg (95% C.I. 246-457 mg/kg)  
Females = 283 mg/kg (95% C.I. 182-469 mg/kg)

Based on the LD<sub>50</sub> in the more susceptible female rats, Paraquat Dichloride Technical Concentrate is classified as EPA Toxicity Category II.

For those animals dosed at 100 mg/kg, all animals survived, gained weight and appeared healthy throughout the study period. At necropsy pelvic dilatation of the kidney was noted in 2 animals.

For those animals dosed at 250 mg/kg, 1 males and 2 females were either found dead or humanely killed on days 4 or 7. All surviving animals gained weight by the end of the study period. Signs of toxicity noted prior to death for these animals included decreased activity, dehydration, hypothermia and irregular breathing. For those animals that survived to the end of the study period these symptoms were also noted, but animals recovered by day 6. At necropsy distended caecum, depleted fat, stained eyelids, mottled or dark lungs and stained nasal cavity

was noted in some animals.

For those animals dosed at 400 mg/kg, 3 males and 4 females were either found dead or humanely killed on days 4 or 5. All surviving animals gained weight by the end of the study period. Similar signs of toxicity were noted as stated above, with surviving animals recovering by day 11. At necropsy similar findings were observed as stated above, including dark livers.

For those animals dosed at 600 mg/kg, males only, all animals were either found dead or humanely killed on day 4. Similar signs of toxicity and necropsy findings were observed in these animals.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 401) in the rat. The report states that the animals were housed 5/sex/cage. According to OPPTS Guidelines 870.1100, the animals should be housed individually. These deviations did not affect the overall acceptability of the study.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## RESULTS and DISCUSSION:

Individual animals were dosed as follows:

### Limit Test

| Animal No. | Sex | Dose level<br>(mg/kg) | Sort-Term Outcome | Long-Term Outcome |
|------------|-----|-----------------------|-------------------|-------------------|
| 1410       | M   | 100                   | S                 | S                 |
| 1411       |     |                       | S                 | S                 |
| 1412       |     |                       | S                 | S                 |
| 1413       |     |                       | S                 | S                 |
| 1414       |     |                       | S                 | S                 |
| 1435       | F   |                       | S                 | S                 |
| 1436       |     |                       | S                 | S                 |
| 1437       |     |                       | S                 | S                 |
| 1438       |     |                       | S                 | S                 |
| 1439       |     |                       | S                 | S                 |

|    |   |     |   |   |
|----|---|-----|---|---|
| 10 | M | 250 | S | S |
| 11 |   |     | S | D |
| 12 |   |     | S | S |
| 13 |   |     | S | S |
| 14 |   |     | S | S |
| 35 | F |     | S | S |
| 36 |   |     | S | D |
| 37 |   |     | S | S |
| 38 |   |     | S | D |
| 39 |   |     | S | S |
| 15 | M | 400 | S | S |
| 16 |   |     | S | S |
| 17 |   |     | S | D |
| 18 |   |     | S | D |
| 19 |   |     | S | D |
| 40 | F |     | S | D |
| 41 |   |     | S | D |
| 42 |   |     | S | S |
| 43 |   |     | S | D |
| 44 |   |     | S | D |
| 1  | M | 600 | S | D |
| 2  |   |     | S | D |
| 3  |   |     | S | D |
| 4  |   |     | S | D |
| 5  |   |     | S | D |

S = survival    D = death

A. Mortality - As noted in table.

B. Clinical observations - For those animals dosed at 100 mg/kg, all animals survived, gained

weight and appeared healthy throughout the study period.

For those animals dosed at 250 mg/kg, 1 male and 2 females were either found dead or humanely killed on days 4 or 7. All surviving animals gained weight by the end of the study period. Signs of toxicity noted prior to death for these animals included decreased activity, dehydration, hypothermia and irregular breathing. For those animals that survived to the end of the study period these symptoms were also noted, but animals recovered by day 6.

For those animals dosed at 400 mg/kg, 3 males and 4 females were either found dead or humanely killed on days 4 or 5. All surviving animals gained weight by the end of the study period. Similar signs of toxicity were noted as stated above, with surviving animals recovering by day 11.

For those animals dosed at 600 mg/kg, males only, all animals were either found dead or humanely killed on day 4. Similar signs of toxicity were observed in these animals as noted above.

**C. Gross Necropsy** - For those animals dosed at 100 mg/kg, at necropsy pelvic dilatation of the kidney was noted in 2 animals.

For those animals dosed at 250 mg/kg, at necropsy distended caecum, depleted fat, stained eyelids, mottled or dark lungs and stained nasal cavity was noted in some animals.

For those animals dosed at 400 and 600 mg/kg, at necropsy similar findings were observed as stated above, including dark livers.

**D. Reviewer's Conclusions:** Agree with study author.

**E. Deficiencies:** The report states that the animals were housed 5/sex/cage. According to OPPTS Guidelines 870.1100, the animals should be housed individually. These deviations did not affect the overall acceptability of the study.

**Reviewer:** Breann Hanson  
**Risk Manager (EPA):** Hope Johnson, RM 25

**Date:** July 28, 2004

**STUDY TYPE:** Acute Dermal Toxicity - S-D Rat; OPPTS 870.1200; OECD 402

**TEST MATERIAL:** Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid)

**CITATION:** Hutchinson, A. (2002) Paraquat Technical Acute Dermal Toxicity (Limit) Test in Rats. Study Number: 501197. Unpublished study prepared by Inveresk Research. February 12, 2002. MRID 46098803.

**SPONSOR:** Sinon Corporation, 111, Chuang-Shan Road, Ta-Tu Hsiang, Tacichung Hsien 432 Taiwan, ROC

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 46098803), 5/sex of Sprague-Dawley rats (Age: 8 weeks; Weight: 256-279 g males, 195-230 g females; Source: Harlan UK Limited, Bicester) were dermally exposed to a single application of Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid) at 2,000 mg/kg. The test material was applied, as received, to the dorsal area and spread evenly over the trunk, covering at 5% of the animal's BSA, and covered with a gauze patch and secured with semi-occlusive tape for 24 hours. Individual body weights were recorded prior to testing and weekly thereafter. Clinical checks for toxicity were made frequently post-dosing on the initial study day, and at least daily thereafter for 15 days. Checks for mortality were made twice daily. All animals were necropsied on study day 15.

Dermal LD<sub>50</sub> Males => 2,000 mg/kg  
Females => 2,000 mg/kg  
Combined => 2,000 mg/kg

Based on the lack of mortality at 2,000 mg/kg, Paraquat Technical is classified as EPA Toxicity Category III.

All animals survived and gained weight throughout the study. The only clinical signs of toxicity noted, red discharge from the nose and eyes, were observed on the initial study day post-dosing. No gross internal findings were observed at necropsy.

This acute dermal study is classified acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat. The report states that the animals were covered with the test substance over 5% of their BSA. According to OPPTS Guidelines 870.1300, the animals should be covered over 10% of their BSA. These deviations did not affect the overall acceptability of the study.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality



statements were provided.

## RESULTS and DISCUSSION:

| Dose (mg/kg) | Mortality/Number Tested |         |          |
|--------------|-------------------------|---------|----------|
|              | Males                   | Females | Combined |
| 2000         | 0/5                     | 0/5     | 0/10     |

A. **Mortality** - None, as noted in table.

B. **Clinical observations** - All animals survived and gained weight throughout the study. The only clinical signs of toxicity noted, red discharge from the nose and eyes, were observed on the initial study day post-dosing.

C. **Gross Necropsy** - No gross internal findings were observed at necropsy.

D. **Reviewer's Conclusions**: Agree with study author.

E. **Deficiencies**: The report states that the animals were covered with the test substance over 5% of their BSA. According to OPPTS Guidelines 870.1300, the animals should be covered over 10% of their BSA. These deviations did not affect the overall acceptability of the study.

**Reviewer:** Breann Hanson  
**Risk Manager (EPA):** Hope Johnson, RM 25

**Date:** July 28, 2004

**STUDY TYPE:** Acute Inhalation Toxicity - S-D Rat; OPPTS 870.1300; OECD 403

**TEST MATERIAL:** Paraquat 45% Technical (AI: 45.9%; Batch No.: OFE0016; green liquid)

**CITATION:** Anderson, B. (2003) Paraquat Technical Acute Inhalation Toxicity Study in Rats. Study Number: 661855. Unpublished study prepared by Inveresk Research. June 12, 2003. MRID 46098804.

**SPONSOR:** Sinon Corporation, 111, Chuang-Shan Road, Ta-Tu Hsiang, Tacichung Hsien 432 Taiwan, ROC

**EXECUTIVE SUMMARY:** In an acute inhalation toxicity study (MRID 46098804), 5/sex/group Sprague Dawley rats (Age: 7-10 weeks; Weight: 200-339 g males; 165-238 g females; Source: Charles River UK Limited, Kent, England) were exposed nose-only via the inhalation route to Paraquat 45% Technical (AI: 45.9%; Batch No.: OFE0016; green liquid) for 4 hours at concentrations of either 0.0019 mg/L (group 1), 0.0004 mg/L (group 2), or 0.0011 mg/L (group 3). The test substance was used in its original form as a liquid aerosol. Individual body weights were recorded prior to testing and for surviving animals on days 2, 4, 7, 10, and 14. Animals found dead prior to study termination or prematurely killed were weighed after death. The animals were observed for clinical signs of toxicity continuously during the exposure period and clinical signs were noted every 30 minutes, frequently 1-2 hours post-dosing, and at least once daily thereafter for 14 days. A gross necropsy examination was performed on all the animals. The  $LC_{50}$  was calculated via probit analysis based on Finney (1971). No analytical or gravimetric analysis was performed.

$LC_{50}$  Males = 0.0007 mg/L  
 $LC_{50}$  Females => 0.0007 mg/L  
 $LC_{50}$  Combined => 0.0007 mg/L

Based on the  $LC_{50}$  of 0.0007 mg/L, Paraquat 45% Technical is classified as EPA Toxicity Category I.

For those animals dosed at 0.0019 mg/L (group 1), no clinical signs were noted during exposure. Clinical signs of toxicity noted immediately after exposure included wet and unkept appearance for all animals, and hunched posture, staining around the head in males. One animal was noted to have wheezing respiration. At 24 hours all animals also were noted to have laboured breathing and all males had noisy respiration. During the next 24 hours surviving animals also showed signs of piloerection. By the end of the second day post-exposure all animals had died or been killed based on humane grounds. Animals surviving to early termination showed notable weight loss. At necropsy all animals were noted to have reddened lungs, 4 animals had spongy lung

lobes, 1 male had reddened testes, 1 male had pelvic dilation of the kidney and 1 female had fluid in the lumen of the trachea.

For those animals dosed at 0.0004 mg/L (group 2), no clinical signs were noted during exposure. Clinical signs of toxicity noted immediately after exposure included unkempt appearance, hunched posture and staining around the head, eyes and/or snout. The unkempt appearance persisted for 1-2 hours post-exposure. No clinical signs of toxicity were noted after this period. All animals gained weight during the study. At necropsy 1 animal was noted to have dark red foci of several lung lobes. No gross necropsy findings were found for the other test animals.

For those animals dosed at 0.0011 mg/L (group 3), no clinical signs were noted during exposure. Clinical signs of toxicity noted immediately after exposure included unkempt appearance in all animals and staining around the head, eyes or snout and wheezing respiration in other animals. 2 animals showed no abnormal signs 1-2 hours post-exposure. 24 hours post-exposure all males and 1 female appeared normal. 48 hours post-exposure 2 males and 1 female were found dead. Surviving animals were noted with unkempt appearance, staining, laboured breathing, hunched posture and/or piloerection, thinness and wheezing respiration. By day 4 post-exposure all animals had died or been killed based on humane grounds. Animals surviving to early termination showed weight loss. At necropsy 3 animals were noted to have reddened lungs and a froth filled trachea, 7 were noted with dark lungs, 3 animals had spongy lung lobes and 3 were noted with staining around the head and muzzle.

**This acute inhalation study is classified as unacceptable. It does not satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat. Although the study is being classified as unacceptable, TRB does not require the test to be repeated due to the toxicity of the test substance. It is classified as toxicity category I. Analytical or gravimetric analysis must be performed in inhalation studies.** Also, the report states that some of the animals were subjected to the start of the study at 7 weeks of age. According to OPPTS Guidelines 870.1300, the animals should be tested between the ages of 8-12 weeks. These deviations did not affect the overall acceptability of the study.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## RESULTS and DISCUSSION:

| Nominal<br>Conc. (mg/L) | Actual Conc.<br>(Analytical)<br>(mg/L) | MMAD<br>μm | GSD<br>μm | Mortality/Number Tested |         |          |
|-------------------------|----------------------------------------|------------|-----------|-------------------------|---------|----------|
|                         |                                        |            |           | Males                   | Females | Combined |
| 0.0019                  | not determined                         |            |           | 5/5                     | 5/5     | 10/10    |
| 0.0004                  | not determined                         |            |           | 0/5                     | 0/5     | 0/10     |
| 0.0011                  | not determined                         |            |           | 5/5                     | 5/5     | 10/10    |

### Test Atmosphere / Chamber Description:

|                           |             |             |             |
|---------------------------|-------------|-------------|-------------|
| Nominal Conc:             | 0.0019 mg/L | 0.0004 mg/L | 0.0011 mg/L |
| Chamber Volume:           | unreported  |             |             |
| Airflow:                  | 10 L/min    |             |             |
| Temperature: (mean)       | 19.8 °C     | 19.9 °C     | 20.0 °C     |
| Relative Humidity: (mean) | 34.0 %      | 32.4 %      | 22.2 %      |
| Time to Equilibrium:      | unreported  |             |             |

**Test atmosphere concentration** - Chamber concentrations were estimated by the measured amount of test substance used during the exposure and dividing by the volume of air sampled. No gravimetric estimation of chamber concentration was performed due to the low volume of test substance being used.

**Particle size determination** - No particle size measurements were performed due to the low volume of test substance being used..

**A. Mortality** - As noted in table.

**B. Clinical observations** - For those animals dosed at 0.0019 mg/L (group 1), no clinical signs were noted during exposure. Clinical signs of toxicity noted immediately after exposure included wet and unkempt appearance for all animals, and hunched posture, staining around the head in males. One animal was noted to have wheezing respiration. At 24 hours all animals also were noted to have laboured breathing and all males had noisy respiration. During the next 24 hours surviving animals also showed signs of piloerection. By the end of the second day post-exposure all animals had died or been killed based on humane grounds. Animals surviving to early termination showed notable weight loss.

For those animals dosed at 0.0004 mg/L (group 2), no clinical signs were noted during exposure. Clinical signs of toxicity noted immediately after exposure included unkempt appearance,

hunched posture and staining around the head, eyes and/or snout. The unkempt appearance persisted for 1-2 hours post-exposure. No clinical signs of toxicity were noted after this period. All animals gained weight during the study.

For those animals dosed at 0.0011 mg/L (group 3), no clinical signs were noted during exposure. Clinical signs of toxicity noted immediately after exposure included unkempt appearance in all animals and staining around the head, eyes or snout and wheezing respiration in other animals. 2 animals showed no abnormal signs 1-2 hours post-exposure. 24 hours post-exposure all males and 1 female appeared normal. 48 hours post-exposure 2 males and 1 female were found dead. Surviving animals were noted with unkempt appearance, staining, laboured breathing, hunched posture and/or piloerection, thinness and wheezing respiration. By day 4 post-exposure all animals had died or been killed based on humane grounds. Animals surviving to early termination showed weight loss.

**C. Gross Necropsy** - For those animals dosed at 0.0019 mg/L (group 1), all animals were noted to have reddened lungs, 4 animals had spongy lung lobes, 1 male had reddened testes, 1 male had pelvic dilation of the kidney and 1 female had fluid in the lumen of the trachea.

For those animals dosed at 0.0004 mg/L (group 2), 1 animal was noted to have dark red foci of several lung lobes. No gross necropsy findings were found for the other test animals.

For those animals dosed at 0.0011 mg/L (group 3), 3 animals were noted to have reddened lungs and a froth filled trachea, 7 were noted with dark lungs, 3 animals had spongy lung lobes and 3 were noted with staining around the head and muzzle.

**D. Reviewer's Conclusions:** Agree with study author.

**E. Deficiencies:** This acute inhalation study is classified as **unacceptable**. It **does not** satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat. Although the study is being classified as unacceptable, **TRB does not require the test to be repeated due to the toxicity of the test substance**. It is classified as toxicity category I. Analytical or gravimetric analysis must be performed in inhalation studies. Also, the report states that some of the animals were subjected to the start of the study at 7 weeks of age. According to OPPTS Guidelines 870.1300, the animals should be tested between the ages of 8-12 weeks. These deviations did not affect the overall acceptability of the study.

**Reviewer:** Breann Hanson  
**Risk Manager (EPA):** Hope Johnson, RM 25

**Date:** July 28, 2004

**STUDY TYPE:** Primary Eye Irritation - NZW Rabbit, OPPTS 870.2400; OECD 405

**TEST MATERIAL:** Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid)

**CITATION:** Hutchinson, A. (2002) Paraquat Technical Acute Eye Irritation Test in Rabbits.  
Study Number: 501218. Unpublished study prepared by Inveresk Research. February 12, 2002. MRID 46098805.

**SPONSOR:** Sinon Corporation, 111, Chuang-Shan Road, Ta-Tu Hsiang, Tacichung Hsien 432  
Taiwan, ROC

**EXECUTIVE SUMMARY:** In a primary eye irritation study (MRID 46098805), 0.1 mL of Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid) was instilled into the conjunctival sac of the right eye of 3 male young adult New Zealand albino rabbits (Source: Charles River UK Limited, Kent, England). The test substance was applied as received and the untreated right eye served as a control. At first only 1 animal was treated and observed for 24 hours. Due to no severe irritation being noted an additional 2 animals were treated. Animals were then observed at 1, 24, 48, 72 hours and up to 6 days post-instillation. Irritation was scored according to Draize. Animals were checked for mortality twice daily.

In this study, the formulation is systemically toxic to rabbits at dose levels of 32 mg/kg following ocular instillation. Due to early termination of the study the eye irritation potential and its reversibility could not be determined. Paraquat Technical is classified as EPA Toxicity Category I.

No corneal opacity or iritis was noted during the study period. One hour after instillation, all eyes exhibited conjunctivitis (scores 1). At 24 hours more intense conjunctivitis (score 2) was noted in 2/3 eyes, and the remaining eye at 48 hours. Due to severe systemic toxicity, noted through clinical signs like salivation, wet muzzles, lack of appetite and reddening of gums, 2 animals were killed on study day 5, while the remaining animal was killed on study day 6.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

**RESULTS AND DISCUSSION:**

| Observations    | Number "positive"/number tested |     |     |     |      |     |
|-----------------|---------------------------------|-----|-----|-----|------|-----|
|                 | Hours                           |     |     |     | Days |     |
|                 | 1                               | 24  | 48  | 72  | 5    | 6   |
| Corneal Opacity | 0/3                             | 0/3 | 0/3 | 0/3 | 0/2  | 0/1 |
| Iritis          | 0/3                             | 0/3 | 0/3 | 0/3 | 0/2  | 0/1 |
| Conjunctivae:   |                                 |     |     |     |      |     |
| Redness*        | 0/3                             | 2/3 | 3/3 | 3/3 | 1/2  | 1/1 |
| Chemosis*       | 0/3                             | 0/3 | 0/3 | 0/3 | 0/2  | 0/1 |
| Discharge*      | 0/3                             | 0/3 | 3/3 | 3/3 | 2/2  | 1/1 |

\*Score of 2 or more required to be considered "positive"

<sup>a</sup> Due to early termination, not all animals were tested on days 5 and 6.

**A. Observations** - No corneal opacity or iritis was noted during the study period. One hour after instillation, all eyes exhibited conjunctivitis (scores 1). At 24 hours more intense conjunctivitis (score 2) was noted in 2/3 eyes, and the remaining eye at 48 hours. Due to severe systemic toxicity, noted through clinical signs like salivation, wet muzzles, lack of appetite and reddening of gums, 2 animals were killed on study day 5, while the remaining animal was killed on study day 6.

**B. Reviewer's Conclusions:** Agree with the study author.

**Reviewer:** Breann Hanson  
**Risk Manager (EPA):** Hope Johnson, RM 25

**Date:** July 28, 2004

**STUDY TYPE:** Primary Dermal Irritation - NZW Rabbit; OPPTS 870.2500; OECD 404

**TEST MATERIAL:** Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid)

**CITATION:** Hutchinson, A. (2002) Paraquat Technical Acute Dermal Irritation Test in Rabbits.  
Study Number: 501202. Unpublished study prepared by Inveresk Research. February 12, 2002. MRID 46098806.

**SPONSOR:** Sinon Corporation, 111, Chuang-Shan Road, Ta-Tu Hsiang, Tacichung Hsien 432  
Taiwan, ROC

**EXECUTIVE SUMMARY:** In a primary dermal irritation study (MRID 46098806), 3 male young adult New Zealand albino rabbits (Source: Harlan UK Limited, Bicester) were dermally exposed to 0.5 mL of Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid). The test substance was applied as received onto a gauze patch, placed on the dorsal trunk of each animal and secured with a semi-occlusive tape and bandage for 4 hours. Animals were then observed for 72 hours. Dermal irritation was scored according to the Draize system at 1, 24, 48 and 72 hours post-patch removal. A dry control patch was also applied to each animal.

In this study, the formulation is non-irritating to the skin. Paraquat Technical is classified as EPA Toxicity Category IV.

No erythema or edema were noted at any point during the study.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.



**RESULTS and DISCUSSION:**

**INDIVIDUAL SKIN IRRITATION SCORES**

**ERYTHEMA/EDEMA**

| Animal Number                          | Sex | Hours |     |     |     |
|----------------------------------------|-----|-------|-----|-----|-----|
|                                        |     | 1     | 24  | 48  | 72  |
| 1                                      | M   | 0/0   | 0/0 | 0/0 | 0/0 |
| 2                                      | M   | 0/0   | 0/0 | 0/0 | 0/0 |
| 3                                      | M   | 0/0   | 0/0 | 0/0 | 0/0 |
| Severity of Irritation -<br>Mean Score |     | 0/0   | 0/0 | 0/0 | 0/0 |

A. Observations - No erythema or edema were noted at any point during the study..

B. Results - Test substance is non-irritating to the skin.

C. Reviewer's Conclusions - Agree with study author.

**Reviewer:** Breann Hanson  
**Risk Manager (EPA):** Hope Johnson, RM 25

**Date:** July 28, 2004

**STUDY TYPE:** Dermal Sensitization - Guinea Pig; OPPTS 870.2600; OECD 406

**TEST MATERIAL:** Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid)

**CITATION:** Hutchinson, A (2002) Paraquat Technical Buehler Test in Guinea Pigs for Delayed Skin Sensitization Potential. Study Number: 501223. Unpublished study prepared by Inveresk Research. February 12, 2002. MRID 46098807.

**SPONSOR:** Sinon Corporation, 111, Chuang-Shan Road, Ta-Tu Hsiang, Tacichung Hsien 432 Taiwan, ROC

**EXECUTIVE SUMMARY:** In a dermal sensitization study (MRID 46098807) with Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid), 30 female young adult Dunkin-Hartley guinea pigs (Weight: 447-566 g; Source: David Hall Limited, Staffordshire, UK) were tested using the Buehler method. The test was initially set up for the Magnusson-Klingman Test method, but due to severity of clinical signs noted during the dose ranging study the design was changed to that of a Buehler Test. Three times a week for 3 weeks, 0.5 mL of a 15% test substance formulation in distilled water was applied to the left flank under a patch and held in contact with occlusive tape and foil to 20 test animals. After 6 hours of exposure, the chambers were removed and the test sites cleaned of residual test material. 24 hours after each induction the animals were scored for dermal irritation. A set of 10 naive control guinea pigs were treated with 0.5 mL of vehicle (distilled water). Two weeks after the last induction dose a challenge dose of 0.5 mL of 15% test substance formulation in distilled water was applied to the right flank of the test and control animals for 6 hours. A control patch with vehicle only was also applied to each animal. Approximately 24 and 48 hours after challenge, the animals were graded for dermal irritation. The 15% test substance formulation in distilled water was previously determined to be the highest non-irritating concentration to be used for both the induction and challenge doses. The animals were observed for mortality twice daily during the study. The procedures were validated using Hexylcinnamaldehyde (HCA) as the positive control substance.

During the dose ranging study for the intradermal injections for the Magnusson-Klingman Test, severe clinical signs including laboured breathing, subdued behaviour, hunched posture and unwillingness to move were noted in the animal that received 0.5, 1, 2 and 5% Paraquat Technical. The animal was killed after the 24 hour observation period. In the animal receiving only 0.5 and 1% Paraquat Technical intense erythema and swelling was noted up to 72 hours. Based on these reactions the study design was changed to that of a Buehler Test. There were no skin reactions in any of the test or control animals during the induction or challenge phases of the Buehler Test.

Based on the results of this study, Paraquat Technical does not have to be labeled as a dermal

sensitizer:

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal sensitization study (OPPTS 870.2600; OECD 406) in the Guinea pig .

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## **I. PROCEDURE**

**A. Induction** - Three times a week for 3 weeks, 0.5 mL of a 15% test substance formulation in distilled water was applied to the left flank under a patch and held in contact with occlusive tape and foil to 20 test animals. After 6 hours of exposure, the chambers were removed and the test sites cleaned of residual test material. 24 hours after each induction the animals were scored for dermal irritation.

**B. Challenge** - Two weeks after the last induction dose a challenge dose of 0.5 mL of 15% test substance formulation in distilled water was applied to the right flank of the test animals for 6 hours. A control patch with vehicle only was also applied to each animal. Approximately 24 and 48 hours after challenge, the animals were graded for dermal irritation.

**C. Naive Controls** - A naive control group of 10 animals were tested with 0.5 mL of vehicle during induction and 0.5 mL of 15% test substance formulation in distilled water at challenge.

## **II. RESULTS and DISCUSSION:**

**A. Reactions and duration** - There were no skin reactions in any of the test or control animals during the induction or challenge phases.

**B. Positive control** - Results were appropriate with HCA study to validate test procedures. The most recent validation of this procedure was completed July 2, 2001. The last date of the dermal sensitization test for Paraquat Technical was October 15, 2001.

**C. Reviewer's Conclusions:** Agree with study author.

1. DP BARCODE: D299079
2. PC CODE: 061601
3. CURRENT DATE: 28/JUL/2004
4. TEST MATERIAL:

Paraquat Dichloride Technical Concentrate (Paraquat: 33.0%; batch reference: F42; brown/black liquid) <sup>a</sup>

Paraquat Technical (AI: 45.9%; Batch No.: OFE0016; green liquid) <sup>b</sup>

Paraquat 45% Technical (AI: 45.9%; Batch No.: OFE0016; green liquid) <sup>c</sup>

| Study/Species/Lab<br>Study # /Date                                                             | MRID     | Results                                                        | Tox.<br>Cat. | Core<br>Grade |
|------------------------------------------------------------------------------------------------|----------|----------------------------------------------------------------|--------------|---------------|
| Acute oral toxicity/rat <sup>a</sup><br>Zeneca Central Toxicology Lab<br>CTL/P/4424/09-30-1994 | 43685001 | LD <sub>50</sub> = 283 mg/kg<br>(females)                      | II           | A             |
| Acute dermal toxicity/rat <sup>b</sup><br>Inveresk Research<br>501197/02-12-2002               | 46098803 | LD <sub>50</sub> > 2,000 mg/kg<br>(males, females<br>combined) | III          | A             |
| Acute inhalation toxicity/rat <sup>c</sup><br>Inveresk Research<br>661855/06-12-2003           | 46098804 | LC <sub>50</sub> = 0.0007 mg/L<br>(males, females<br>combined) | I            | U             |
| Primary eye irritation/rabbit <sup>b</sup><br>Inveresk Research<br>501218/02-12-2002           | 46098805 | early termination of test<br>due to systemic toxicity          | I            | A             |
| Primary dermal irritation/rabbit <sup>b</sup><br>Inveresk Research<br>501202/02-12-2002        | 46098806 | non-irritant                                                   | IV           | A             |
| Dermal sensitization/guinea pig <sup>b</sup><br>Inveresk Research<br>501223/02-12-2002         | 46098807 | is not a sensitizer                                            | —            | A             |

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived

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July 14, 2004

Gautam Srinivasan, Attorney  
Pesticides and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
Ariel Rios Building, Mail Code 2333A  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Syngenta's Petition to Deny Sinon's Application to Register Paraquat; Syngenta's  
Response to Sinon's June 30th Letter

Dear Mr. Srinivasan:

Petitioner Syngenta Crop Protection, Inc. (Syngenta) writes in response to the letter to EPA dated June 30, 2004 from counsel for Sinon Corporation (Sinon). Sinon requests immediate action by your office on Syngenta's January 23, 2004 Petition to Deny Sinon's Application to Register Paraquat Technical Concentrate (the Petition). Syngenta responds to address inaccuracies in Sinon's letter, as well as Sinon's mischaracterizations about the Petition and the petition process at EPA.

Syngenta's Petition provided facts that call into question Sinon's fitness to hold a paraquat registration and raise enforcement issues. In addition, Syngenta has identified serious legal inadequacies in Sinon's application that unfortunately require EPA's attention and consideration. These are issues of Sinon's own making arising from business choices and regulatory decisions that Sinon has made over a period of years, and the way in which it decided to try to apply for registration of a new source of technical paraquat. Sinon offers no basis to short circuit EPA's review of the issues raised in the Petition other than its desire to begin selling paraquat under a new registration in the United States as quickly as possible. Sinon's business plans are not a basis to make such demands which are not based in law.

As stated in EPA's February 19, 2004 letter to the parties, "[a]lthough the mere filing of a Petition to deny registration does not by itself require EPA to suspend action on an application for registration that is the subject of the Petition, the above-referenced Petition presents specific arguments that the Agency must resolve as a matter of course when considering Sinon's application." Letter from G. Srinivasan to K. Szmuszkowicz and E. Brown of February 19, 2004 at 2. The Petition and its exhibits address in detail specific concerns regarding Sinon and its application that must be investigated and resolved before Sinon can receive a paraquat registration. Most of these issues went unaddressed by Sinon in its March 22, 2004 response and certainly were not resolved by the comments that were provided.

Gautam Srinivasan, Esq.  
July 14, 2004  
Page 2

Specifically, Syngenta's Petition identifies three major problems presented by Sinon's paraquat application:

- Sinon's fitness to hold a paraquat registration in light of unresolved questions pertaining to its supplying paraquat to Marman USA, Inc. (Marman). As discussed in Syngenta's May 10, 2004 reply, public records show that Sinon has continued to ship paraquat to Marman this year, seemingly in violation of FIFRA;
- Sinon's ability to show that its paraquat product is substantially similar to Syngenta's product, both with regard to Sinon's ability to produce commercial quantities of paraquat without harmful impurities as well as its ability to ensure that pesticides containing its paraquat match the safety features which EPA insists upon to sell paraquat in the United States, such as inclusion of an EPA-approved emetic equivalent to Syngenta's; and
- Sinon's failure to provide Syngenta an offer to pay compensation for its reliance on Syngenta's data, which standing alone should prevent further processing of the application. The failure to provide timely offers to pay is a serious and pressing legal concern, and has been raised in this and at least two other Syngenta petitions before EPA.

These issues are particularly important to EPA and the public here because paraquat is a widely-used herbicide, which both EPA and Syngenta have worked hard to steward. In any event, applicants for registration of all pesticides must strictly comply with all requirements of FIFRA.

Finally, Syngenta strongly objects to Sinon's spurious comments that the Petition is "meritless" and that it is part of "anti-competitive strategies" that the Agency may be complicit in. Syngenta is exercising its express right as a data submitter to petition to deny an application pursuant to 40 C.F.R. § 152.99. Moreover, EPA is performing its statutory duty to review the Petition and determine Sinon's compliance with FIFRA as well as its fitness to hold a pesticide registration. *See, e.g., EPA, Termilind Ltd: Notice and Order of Revocation of Registration*, 62 Fed. Reg. 61890 (November 19, 1997) (discussing requirements for fitness to hold a pesticide registration).

BEVERIDGE & DIAMOND, P. C.

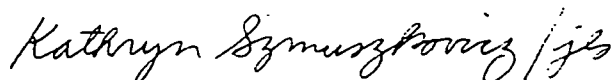
Gautam Srinivasan, Esq.

July 14, 2004

Page 3

Syngenta understands and appreciates the resources and time the Agency must devote to the Petition. Syngenta too is often an applicant for FIFRA registrations and must undergo all the scrutiny attendant to such applications. Syngenta simply asks that Sinon also be held to EPA's high standards for registration.

Sincerely,



Kathryn E. Szmuszkovicz  
Counsel for Syngenta

cc: J. Jones  
L. Rossi (EPA)  
D. Stubbs (EPA)  
J. Tompkins (EPA)  
Y. Hopkins (EPA)  
A. Pontius (EPA)  
C. Eichenwald (EPA)  
B. Dyer (EPA)  
C. Stafford (Counsel for Sinon)

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of July, 2004, copies of the attached *Syngenta's Petition to Deny Sinon's Application to Register Paraquat; Syngenta's Response to Sinon's June 30th Letter* were delivered to the following by the method specified below:

Gautam Srinivasan, Attorney  
Pesticides and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
Ariel Rios Building, Mail Code 2333A  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Hand Delivery

Cresence Stafford  
Counsel for Sinon Corporation  
Wright & Sielaty, P.C.  
1990 Old Bridge Road, Suite 202  
Lake Ridge, VA 22192-2383

FedEx

  
Katherine A. Shortell





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUL 8 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Dr. Elizabeth A. Brown  
ChemReg International, LLC  
Consultant for: Sinon Corporation  
1990 Old Bridge Rd, Suite 201  
Lake Ridge, VA 22192-2383

Dear Dr. Brown:

Subject: Paraquat Technical Concentrate  
EPA Registration Number 70552-R  
Product Chemistry Review

The product chemistry studies, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, do not meet the data requirements as specified in 40 CFR 158.155 & 158.190. See the attached product chemistry review from the Technical Review Branch (TRB) for details concerning data gaps.

The data gaps listed in the TRB memo need to be addressed before this product may be registered. Please note that the one-year storage stability study (830.6317) and corrosion characteristics (830.6320) study will be considered conditions of registration if not completed and submitted to the Agency by the registration date.

If you have any questions, please contact Hope Johnson at 703-305-5410.

Sincerely,

A handwritten signature in black ink, appearing to read "James A. Tompkins".

James A. Tompkins  
Product Manager 25  
Herbicide Branch  
Registration Division (7505C)

NON - FEE

Date: July 1, 2004

SUBJECT: Product Chemistry Review of Paraquat Technical Concentrate

FROM: Debra Rate  
Product Chemistry Team  
Technical Review Branch/RD (7505C)

*SBR 7/1/04*  
*Debra N. Rate 7/1/04*

TO: Jim Tompkins / Hope Johnson, RM 25  
Herbicide Branch / RD (7505C)

DP BARCODE: 299077

EPA REG. NO.: 70552-R

PRODUCT: Paraquat Technical Concentrate

PCC : 061601

REGISTRANT: Sinon Corp.

USE: Herbicide

#### INTRODUCTION:

The registrant has submitted the product chemistry data in support of the registration application for Paraquat technical concentrate produced by Sinon Corp. facility located in Taichung Hsien, Taiwan. The applicant has included a CSF for basic formulation (dated 09/12/03) and the product label. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 100-1067. The data have been submitted under MRID Nos. 460988-01 and 460988-02. The TRB has been asked to evaluate the product chemistry data submitted and determine similarity with the registered product.

#### SUMMARY OF FINDINGS:

1. The registrant has submitted a CSF for basic formulation (dated 09/12/03) for paraquat technical concentrate. The nominal concentration (46.2%) of the AI concurs with the product label claim nominal concentration of 46.2%. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively. [MRID No. 460988-01]
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) do not satisfy the data requirements of 40CFR§ 158.160. The registrant has provided the product specifications data on all the starting materials used for the production of this technical. However, the registrant must provide additional information on the synthesis of one of the impurities submitted on the CSF(dated 09/12/03). [MRID No. 460988-01]
3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) do not satisfy the data requirements for 40CFR§158.162. The manufacturing process for the Paraquat technical has been described in details, but did not include the types of reactors used and the time required for each step of the reaction.[MRID No. 460988-01]
4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.167 conditionally. The registrant has described the mechanism of formation of impurities present in the technical, except one that is listed on the CSF(dated 09/12/03), during the synthesis of this technical. The five batch analysis concurs with the discussion provided on the formation of impurities. The presence and formation of any impurity of toxic concern during the synthesis of paraquat technical was not indicated during the discussion. The registrant must provide information on the mechanism of formation of the impurity listed on the CSF and list on the CSF the other impurities discussed. [MRID No. 460988-01]

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

BARCODE: 299077; Reg. No. : 70552-R PRODUCT: Paraquat Technical Concentrate

5. The data submitted corresponding to the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.170. Five representative batches of the technical product were analyzed for percent active ingredient and the organic impurities by HPLC/UV(254 nm), GC/FID and Ion chromatography. [MRID No. 460988-01]

6. The data submitted corresponding the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The HPLC/UV(254 nm) method was used to assay the active ingredient in the TGA/MUP. The method was validated for linearity of response, system precision, and assay recovery. [MRID No. 460988-01]

7. The data submitted corresponding to 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190, except for the one year storage stability (830.6320) and corrosion characteristics (830.6320) studies which are in progress. The results of the accelerated storage stability (14 days at 54°C and 28 days in constant light) study did not show any signs of decomposition and corrosion associated with the TGA/MUP. [MRID No. 460988-01]

**CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for Paraquat technical and has concluded that:

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A and Subgroup B satisfy the data requirements of 40CFR§158.155 to 158.190 and are acceptable, except for the followings:

830 Series Subgroup A

(a). 830.1550 (Product identity and composition):

[REDACTED] One of the impurities listed on the CSF is not discussed further.

The registrant must address this.

(b). 830.1620 (description of production process): The production process has been described, however more detail is needed about the reactors and equipment used in the production process. Also, a brief description of the quality control steps is required.

(c). 830.1670 (discussion on the formation of impurity): The registrant has not provided the complete mechanisms of formation, identification and quantitation of all the impurities during formulation of the TGA/MUP. One of the impurities listed on the CSF is not discussed in MRID No. 460988-01.

(d). 830.1750 (Certified limits): The certified limits of one of the inert ingredients was not calculated according to Agency Standards (40CFR§158.175(b)(2)). The registrant must provide justification for this deviation.

830 Series Subgroup B

(a). 830.6317 (one year storage stability) and 830.6320 (corrosion characteristics): the results of one year study must be submitted on completion.

2. The CSF for basic formulation (dated 09/12/03) is not acceptable. The bulk density is missing from box 7, and the flash point is missing from box 9. The registrant must be sure that the % of all of the ingredients used in the formulation add up to 100%.

3. The proposed product could be considered substantially similar to the registered product with Reg. No. 100-1067 from a Product Chemistry view point provided that the above deficiencies (Subgroup A (a-d), CSF and Subgroup B (a)) are met.

BARCODE: 299077; Reg. No. : 70552-R PRODUCT: Paraquat Technical Concentrate

Common Name: Paraquat Dichloride

Chemical name: 1,1'-dimethyl, 4,4'-bipyridinium dichloride

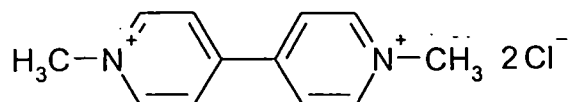
CAS No.: 1910-42-5

PC Code No.: 061601

Empirical formula:  $C_{12}H_{14}N_2 \cdot 2Cl$

Molecular Weight:: 257.2

Structural formula:



**\*MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED\***

ATTACHMENT II

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

|                                |                                             |
|--------------------------------|---------------------------------------------|
| Chemical Name (IUPAC, CAS)     | 1,1'-dimethyl, 4,4'-bipyridinium dichloride |
| Chemical Number (CAS; PC Code) | CAS No. 1910-42-5<br>PC Code: 061601        |
| Registration/Symbol No.        | 70522-R                                     |
| Type of Product (T, MP, EP)    | 46.2% TGAI/ MP                              |
| DP Barcode                     | 299077                                      |
| Reviewer                       | Debra Rate                                  |
| Branch Chief                   | Deborah McCall                              |

| Table 1: Manufacturing and Impurity Data for Paraquat Technical Concentrate |                                                  |                      |        |                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------------------------------------------------------|--------------------------------------------------|----------------------|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GLN                                                                         | Requirement                                      | MRID                 | Status | Details and/or Deficiency                                                                                                                                                                                                                                                                                                                                                                                            |
| 830.1550                                                                    | Product identity and composition                 | Basic CSF (09/12/03) | N      | The NC of AI (46.2%) is supported by 5 batch analysis & concurs with the product label claim of 46.2%. The bulk density is missing from box 7, and the flash point is missing from box 9. The registrant must be sure that the % of all of the ingredients used in the formulation add up to 100%.<br>[REDACTED] One of the impurities listed on the CSF is not discussed further. The registrant must address this. |
| 830.1600                                                                    | Description of materials used to produce product | 460988-01            | A      | The product specification sheets (MSDS) for each of the starting materials have been provided by registrant.                                                                                                                                                                                                                                                                                                         |
| 830.1620                                                                    | Description of production process                | 460988-01            | U      | The production process has been described, however more detail is needed about the reactors and equipment used in the production process. Also, a brief description of the quality control steps is required. The reaction conditions are given, and the molar ratios of each of the reagents used have been reported.                                                                                               |
| 830.1670                                                                    | Discussion of formation of impurities            | 460988-01            | U      | The registrant has not provided the complete mechanisms of formation, identification and quantitation of all the impurities during formulation of the TGAI/MUP. One of the impurities listed on the CSF is not discussed in MRID No. 460988-01. No toxic impurity was reported during the synthesis of the TGAI/MUP.                                                                                                 |
| 830.1700                                                                    | Preliminary analysis                             | 460988-01            | A      | Registrant has provided 5 batch analysis for the TGAI. The AI and impurities were assayed by using HPLC/UV, GC and ion chromatography techniques. The analytical methods have been validated for system precision, linearity of response & assay recovery.                                                                                                                                                           |

Table 1: Manufacturing and Impurity Data for Paraquat Technical Concentrate

| GLN                                                                                                                                                                       | Requirement                   | MRID                    | Status | Details and/or Deficiency                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 830.1750                                                                                                                                                                  | Certified limits              | Basic CSF<br>(09/12/03) | U      | The proposed certified limits for the TGAI were with in standard certified limits. The NC & UCL for the impurities have been provided on the CSF. The certified limits of one of the inert ingredients was not calculated according to Agency Standards (40CFR§158.175(b)(2). The registrant must provide justification for this deviation. |
| 830.1800                                                                                                                                                                  | Enforcement analytical method | 460988-01               | A      | The HPLC/UV (254 nm) method was used for the assay of the AI in technical. The method was validated for linearity, accuracy and precision.                                                                                                                                                                                                  |
| A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.; G = Data gap; I = In progress or need upgrade;<br>U = Up-grade(additional information required) |                               |                         |        |                                                                                                                                                                                                                                                                                                                                             |

BARCODE:299077; Reg. No.:70552-R PRODUCT: Paraquat Technical Concentrate

Table 2: Physical and Chemical Properties of Paraquat Technical

| GLN      | Requirement                                                           | MRID      | Status | Result or Deficiency                                                                                                                                                     |
|----------|-----------------------------------------------------------------------|-----------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 830.6302 | Color                                                                 | 460988-02 | A      | Light brown (7.5G 4/8 on Munsell System)                                                                                                                                 |
| 830.6303 | Physical state                                                        | 460988-02 | A      | Powder with occasional aggregates                                                                                                                                        |
| 830.6304 | Odor                                                                  | 460988-02 | A      | Not tested due to known hazard rating of paraquat.                                                                                                                       |
| 830.6313 | Stability to normal and elevated temperatures, metals, and metal ions | 460988-02 | A      | The test substance was not considered to be stable at room temperature. The stability of the test substance was not influenced by the presence of iron, tin or aluminum. |
| 830.6314 | Oxidation/reduction: chemical incompatibility                         | 460988-02 | A      | Paraquat is non-oxidizing.                                                                                                                                               |
| 830.6315 | Flammability                                                          | 460988-02 | A      | Paraquat is non-flammable.                                                                                                                                               |
| 830.6316 | Explosibility                                                         | 460988-02 | A      | Did not explode when exposed to heat or mechanical shock.                                                                                                                |
| 830.6317 | Storage stability                                                     | 460988-02 | I      | Accelerated 14 days at 54°C indicate no decomposition and no corrosion. One year study in progress                                                                       |
| 830.6319 | Miscibility                                                           |           | NA     |                                                                                                                                                                          |
| 830.6320 | Corrosion characteristics                                             |           | I      | 1 year in progress                                                                                                                                                       |
| 830.7000 | pH                                                                    | 460988-02 | A      | PAI = 4.15 TGAI = 4.48                                                                                                                                                   |
| 830.7050 | UV/visible absorption                                                 | 460988-02 | A      | Paraquat PAI was found to have no Molar Extinction Coefficient > 10 above 290nm.                                                                                         |
| 830.7100 | Viscosity                                                             |           | NA     |                                                                                                                                                                          |
| 830.7200 | Melting point                                                         | 460988-02 | A      | >360 °C                                                                                                                                                                  |
| 830.7220 | Boiling point                                                         |           | NA     |                                                                                                                                                                          |
| 830.7300 | Relative Density                                                      | 460988-02 | A      | 1.178 g/cc                                                                                                                                                               |
| 830.7370 | Dissociation constants in water                                       | 460988-02 | A      | None found for Paraquat. Paraquat dichloride is considered to be 100% dissociated in aqueous solutions.                                                                  |
| 830.7550 | Partition coefficient                                                 | 460988-02 | A      | <-2                                                                                                                                                                      |
| 830.7840 | Water solubility:                                                     | 460988-02 | A      | Potassium Hydrogen Phthalate (pH4):529 mg/g<br>KPO4(pH 7):511 mg/g<br>Boric Acid (pH 9):480 mg/g<br>Water:464 mg/g                                                       |
| 830.7950 | Vapor pressure                                                        | 460988-02 | A      | 2.3 X 10 <sup>-13</sup> Pa @ 25 °C                                                                                                                                       |

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.; G = Data gap; I = In progress or need upgrade

---

Registration File No. 70552-1

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Page \_\_\_\_\_ is not included in this copy.

Pages 181 through 186 are not included in this copy.

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The material not included contains the following type of information:

- \_\_\_\_\_ Identity of product inert ingredients.
  - \_\_\_\_\_ Identity of product impurities.
  - ☒ Description of the product manufacturing process.
  - ☒ Description of quality control procedures.
  - \_\_\_\_\_ Identity of the source of product ingredients.
  - \_\_\_\_\_ Sales or other commercial/financial information.
  - \_\_\_\_\_ A draft product label.
  - \_\_\_\_\_ The product confidential statement of formula.
  - \_\_\_\_\_ Information about a pending registration action.
  - \_\_\_\_\_ FIFRA registration data.
  - \_\_\_\_\_ The document is a duplicate of page(s) \_\_\_\_\_.
  - \_\_\_\_\_ The document is not responsive to the request.
- 

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---



# ChemReg

INTERNATIONAL, LLC

460988-00

1990 OLD BRIDGE ROAD, SUITE 201  
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www.pesticide.net

ELIZABETH A. BROWN, PH.D.

October 16, 2003

Document Processing Desk (APPL)  
U.S. Environmental Protection Agency (7505C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

70552-R

Attn: Jim Tompkins (PM 25)

Re: Application for Registration of "Me-Too" Paraquat Technical Concentrate  
Sinon Corporation, Company Number 70552

Dear Jim:

On behalf of our client, Sinon Corporation, and as discussed during the presubmission meeting with you on July 18, 2003, we are submitting an application for a "me-too" registration of Paraquat Technical Concentrate containing paraquat dichloride (EPA Product Code 61601). This product is substantially similar in composition and labeling to the already registered EPA Reg No. 100-1067 (Paraquat Concentrate ES). It differs in labeling from that product in accordance with your specific verbal direction during the presubmission meeting, in that the permissible use sites are consistent with those determined to be eligible for reregistration in the 1997 RED and approximate the approved label for the now cancelled EPA Reg. No. 1812-424. However, these differences are not such that they would affect a determination of substantial similarity as defined in FIFRA Section 3(c)(3)(B)(i)(I).

Enclosed please find:

- Application form 8570-1
- Confidential Statement of Formula (Form 8570-4)
- Data matrix forms for EPA and public use (Form 8570-35)
- Transmittal bibliography
- Three (3) copies of each submitted study
- Five (5) copies of the proposed label

---

CONSULTANTS TO SUCCESS<sup>SM</sup>

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.



Letter to Jim Tompkins, October 16, 2003, page 2

Please note that we are relying upon the selective cite all method to satisfy data requirements that have not been satisfied by data submitted by Sinon Corporation. Applicable data requirements and determination of acceptable studies is based on the Paraquat Dichloride Reregistration Eligibility Document.

A Certification With Respect to Citation of Data (EPA Form 8570-34) is not included with this letter. A notification as required by 40 CFR §152.93 has been provided to the data submitter(s). Please process this application and notify me when the review is complete. If upon completion of the review the Agency is prepared to issue a registration, the Certification With Respect to Citation of Data will be filed.

Sinon is requesting a waiver from the requirements to assess the stability to metal and metal ions under OPPTS 830.6313, as the product is packaged, stored, and shipped in high density polyethylene and is not in contact with metals or metal ions. The submitted study meets the requirements for stability to normal and elevated temperatures under OPPTS 830.6313.

Please do not hesitate to call me immediately if there are any questions or if anything further is needed.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Anne Brown".

Elizabeth Anne Brown, Ph.D.

cc: Sinon Corporation

# TRANSMITTAL DOCUMENT

## Submitter

Sinon Corporation

Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

\*ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

\*ChemReg International, LLC is the authorized representative for Sinon Corporation

## Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")  
Paraquat Technical Concentrate 70552-x

## Transmittal Date

October 16, 2003

## Submitted Studies

|             | MRID            |                                                                                                                                                                                                       |
|-------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ---         |                 | Administrative Materials                                                                                                                                                                              |
| Document 1: | <b>46098801</b> | Hauswirth, J.W. Sept. 12, 2003. Paraquat Technical. Product Identity, Composition, and Analysis (Group A). Report No. Sinon-Paraquat-A. 187 pages. <i>Contains Confidential Business Information.</i> |
| Document 2: | <b>46098802</b> | Hauswirth, J.W. Oct. 14, 2003. Paraquat Technical. Physical and Chemical Properties (Group B). Report No. Sinon-Paraquat-B. 203 pages.                                                                |
| Document 3: | <b>46098803</b> | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Acute Dermal Toxicity (Limit) Tests in Rats. Report No. Inversek Project Number 501197. 25 pages.                                             |
| Document 4: | <b>46098804</b> | Anderson, B.T.. June 12, 2002. Paraquat Technical. Acute Inhalation Toxicity in Rats. Report No. Inversek Project Number 661855. 37 pages.                                                            |
| Document 5: | <b>46098805</b> | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Acute Eye Irritation in Rabbits. Report No. Inversek Project Number 501218. 25 pages.                                                         |
| Document 6: | <b>46098806</b> | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Acute Dermal Irritation Test in Rabbits. Report No. Inversek Project Number 501202. 23 pages.                                                 |

## TRANSMITTAL DOCUMENT, Continued

|             |                 |                                                                                                                                                                                          |
|-------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Document 7: | <b>46098807</b> | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Buehler<br>Test in Guinea Pigs for Delayed Skin Sensitization Potential.<br>Report No. Inversek Project Number 501223. 32 pages. |
|-------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Company Official

*Judith W. Hauswirth*

Company Name:

ChemReg International, LLC, Authorized Agent for Sinon Corporation

Company Contact:

Judy W. Hauswirth

Phone Number:

703-492-1788

## Paraquat Technical Concentrate

For Formulation of Paraquat Herbicide Products Only

### ACTIVE INGREDIENT

Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride).....46.2%

INERT INGREDIENTS.....53.8%

TOTAL.....100.0%

Contains 3 pounds paraquat cation per gallon

EPA Reg. No. 70552-x

EPA Establishment No. 70552-TWN-001

**KEEP OUT OF REACH OF CHILDREN**

**DANGER – PELIGRO**



**POISON**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• Call Poison Control Center or doctor immediately for treatment advice</li><li>• Have person sip a glass of water if able to swallow</li><li>• Do not induce vomiting unless told to by a poison control center or doctor</li><li>• Do not give anything by mouth to an unconscious person</li></ul> |
| If inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                        |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                            |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"><li>• Take off contaminated clothing</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                                                                                 |
| HOTLINE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                             |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                             |
| NOTE TO PHYSICIANS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                             |
| CALL CHEMTREC 1-800-424-9300 at any hour to obtain toxicology and medical management consultation and paraquat analyses. Prompt treatment is essential and must be initiated immediately before signs and symptoms appear. Symptoms are prolonged and painful and may be delayed for days after swallowing. Treatment may include binding paraquat in the gut with suspensions of clay or charcoal; and/or removal of paraquat from the blood by prolonged charcoal hemoperfusion or continuous hemodialysis. Probable mucosal damage may contraindicate the use of gastric lavage. |                                                                                                                                                                                                                                                                                                                                             |

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### DANGER – POISON



Fatal if inhaled. May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe spray mist. Do not inhale contaminated dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
  - Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)
  - Full face shield
  - Chemical-resistant gloves, Category A
  - Apron and waterproof footwear
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

### ENVIRONMENTAL HAZARDS

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

### PHYSICAL AND CHEMICAL HAZARD

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

### SPILLAGE DURING TRANSPORT

**Emergency Action:** Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

**KEEP PUBLIC AND ANIMALS** away from area. **MARK ROADS AND WARN OTHER ROAD USERS.**  
**WEAR** face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid; using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

(192)

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into a herbicide for the following uses:

- (1) Terrestrial Food: **Alfalfa, Almond, Asparagus, Beans Dry** (Adzuki beans, Asparagus bean, Black bean, Broad bean, Field bean, Garbanzo bean, White sweet lupine, White lupine, Kidney bean, Lablab bean, Lima bean, Fava bean, Mung bean, Navy bean, Pinto bean, Rice bean, Snap bean, Tepary bean, Urd bean, Waxbean, Blackeyed pea, Chickpea, Cowpea, Crowder pea, Southern pea, Catjang, Guar), **Berries** (Blackberries, Blueberries, Boysenberries, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry), **Cassavas, Clover, Legumes** (Venvet bean, Lespedeza, Lupine, Sainfoin, Tréfoil, Vetch, Crown Vetch, Milk Vetch), **Corn** (Pop, Field, and Sweet), **Cotton, Grain lupine, Grasses** (pasture and range), **Guava, Hops, Lentil, Mint** (Peppermint, Spearmint), **Onions, Garlic, Passion fruit, Pastures, Peanuts, Pigeon Peas, Pineapple, Potato, Rice, Safflower, Small fruits, Small grains** (Barley, Wheat), **Sorghum** (grain), **Strawberries, Soybeans, Sugar beets, Sugarcane, Sunflower, Sweet lupine, Taniers, Taro, Trees and Vines** (Acerola, Apple, Apricot, Avocado, Banana, Beechnut, Brazil nut, Butternut, Calamondin, Cashew, Cherry, Chestnut, Chinquapin, Citrus Citron, Coffee, Crabapple, Fig, Filbert, Grape, Grapefruit, Hickory nut, Kiwi fruit, Jumquat, Lemon, Lime, Loquat, Macadamia nut, Mandarin, Mayhaw, Nectarines, Olive, Orange (sweet and sour), Papaya, Peach, Pear (oriental), Pecan, Pistachio, Plum, Prune, Pummelo, Quince, Satsuma mandarin, Walnut, Shade and Ornamental trees (such as Arbovitae, Ash, Elm, Oak, Pine, etc.)), **Tylon, Vegetables** (Broccoli, Brussels sprouts, Cabbage, Cantaloupe, Carrot, Cauliflower, Cavalo, Chayote fruit, Chinese cabbage, Chinese wasgourd, Citron melon, Collard, Cucumber, Eggplant, Gherkin, Gourd (edible), Ground cherry, *Momordica* spp., Kale, Kohlrabi, Lettuce, Mizune, Musk melon, Mustard greens, Mustard spinach, Peas, Pepino, Pepper, Pumpkin, Rape greens, Squash, Sweet corn, Tomatillo, Tomato, Turnip, Watermelon, Eggplant, Pepper, Chili pepper, Rubarb), **Yams.**

Terrestrial Nonfood: Conservation Compliance Lands, Conservation Reserve Lands, Federal Set-Aside Lands, Grasses grown for seed, resin soaking (pines), Tree plantation establishment.

- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

#### WARRANTY STATEMENT

SINON CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by Buyer and User. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this product. SINON CORP. makes no warranties of merchantability or of fitness for a particular purpose nor for any other expressed or implied warranty except as stated above.

Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 10-14-2003. NOT EPA APPROVED





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 6, 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MICRO FLO CO  
SINON CORP  
PO Box 5948  
LAKELAND, FL 33807-5948

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 17-OCT-03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 746244

Regulatory Type: Product Registration Section 3 ☐ Pre-submission ☐

Application Type: New Registration ☐

Company: 70552 SINON CORP. ☐

Risk Manager: Registration Division Risk Management Team 25 ☐

Product #: 70552-R Product Name: PARAQUAT TECHNICAL CONCENTRATE

Override: ☐

Me Top Section 3: ☐ Me Top Product Name: ☐

Application Date: 16-Oct-2003 ☐ OPP Rec'd Date: 17-Oct-2003 ☐

Front End Date: 21-Oct-2003 ☐ Risk Manager Send Date: 21-Oct-2003 ☐

Fast Track ☐ Studies ☒ New Ingredient ☐

Recent Description:

Form:

☐

Signature Date:

Form:

☐

Signature Date:



460988-00

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

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MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

October 16, 2003

Document Processing Desk (APPL)  
U.S. Environmental Protection Agency (7505C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

70552-R

Attn: Jim Tompkins (PM 25)

Re: Application for Registration of "Me-Too" Paraquat Technical Concentrate  
Sinon Corporation, Company Number 70552

Dear Jim:

On behalf of our client, Sinon Corporation, and as discussed during the presubmission meeting with you on July 18, 2003, we are submitting an application for a "me-too" registration of Paraquat Technical Concentrate containing paraquat dichloride (EPA Product Code 61601). This product is substantially similar in composition and labeling to the already registered EPA Reg No. 100-1067 (Paraquat Concentrate ES). It differs in labeling from that product in accordance with your specific verbal direction during the presubmission meeting, in that the permissible use sites are consistent with those determined to be eligible for reregistration in the 1997 RED and approximate the approved label for the now cancelled EPA Reg. No. 1812-424. However, these differences are not such that they would affect a determination of substantial similarity as defined in FIFRA Section 3(c)(3)(B)(i)(I).

Enclosed please find:

Application form 8570-1

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Data matrix forms for EPA and public use (Form 8570-35)

Transmittal bibliography

Three (3) copies of each submitted study

Five (5) copies of the proposed label

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# ChemReg

INTERNATIONAL, LLC

Letter to Jim Tompkins, October 16, 2003, page 2

Please note that we are relying upon the selective cite all method to satisfy data requirements that have not been satisfied by data submitted by Sinon Corporation. Applicable data requirements and determination of acceptable studies is based on the Paraquat Dichloride Reregistration Eligibility Document.

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Sinon is requesting a waiver from the requirements to assess the stability to metal and metal ions under OPPTS 830.6313, as the product is packaged, stored, and shipped in high density polyethylene and is not in contact with metals or metal ions. The submitted study meets the requirements for stability to normal and elevated temperatures under OPPTS 830.6313.

Please do not hesitate to call me immediately if there are any questions or if anything further is needed.

Sincerely,



Elizabeth Anne Brown, Ph.D.

cc: Sinon Corporation

# TRANSMITTAL DOCUMENT

## Submitter

Sinon Corporation

Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

\*ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

\*ChemReg International, LLC is the authorized representative for Sinon Corporation

## Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")  
Paraquat Technical Concentrate 70552-x

## Transmittal Date

October 16, 2003

## Submitted Studies

|             | MRID            |                                                                                                                                                                                                       |
|-------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ----        |                 | Administrative Materials                                                                                                                                                                              |
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## TRANSMITTAL DOCUMENT, Continued

|             |                 |                                                                                                                                                                                          |
|-------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Document 7: | <b>46098807</b> | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Buehler<br>Test in Guinea Pigs for Delayed Skin Sensitization Potential.<br>Report No. Inversek Project Number 501223. 32 pages. |
|-------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Company Official

*Judith W. Hauswirth*

Company Name:

ChemReg International, LLC, Authorized Agent for Sinon Corporation

Company Contact:

Judy W. Hauswirth

Phone Number:

703-492-1788

## NEW APPLICATIONS

DATE: 10/21/03

FILE NUMBER: 70552-R

FEP (OPPIN ENTRY) 10/21/03 Rem  
(Initial & date)

FILE ROOM: QA 10/23/03  
(Initial & date)

SIG: KC 10/24/03  
(Initial & date)

FILE ROOM: \_\_\_\_\_  
(Initial & date)

\_\_\_ ASSIGN TO PM \_\_\_ (NO DATA)

☒ JACKET TO SHELF (DATA)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

October 21, 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

ELIZABETH ANNE BROWN  
CHEM REG INTERNATIONAL, LLC  
SINON CORP  
1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VA 22192-2383

PRODUCT NAME: PARAQUAT TECHNICAL CONCENTRATE  
COMPANY NAME: SINON CORP  
EPA FILE SYMBOL: 70552-R  
EPA RECEIPT DATE: 10/17/03

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process and does NOT constitute approval.

If you have any questions, please contact Registration Division, Risk Management Team 25, at (703) 305-5697.

Sincerely,

*Patricia A. Moore*  
Front End Processing Staff  
Information Services Branch  
Information Resources and Services Division

202



NIFT

# ChemReg

INTERNATIONAL, LLC

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

October 16, 2003

Document Processing Desk (APPL)  
U.S. Environmental Protection Agency (7505C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

Attn: Jim Tompkins (PM 25)

Re: Application for Registration of "Me-Too" Paraquat Technical Concentrate  
Sinon Corporation, Company Number 70552

Dear Jim:

On behalf of our client, Sinon Corporation, and as discussed during the presubmission meeting with you on July 18, 2003, we are submitting an application for a "me-too" registration of Paraquat Technical Concentrate containing paraquat dichloride (EPA Product Code 61601). This product is substantially similar in composition and labeling to the already registered EPA Reg No. 100-1067 (Paraquat Concentrate ES). It differs in labeling from that product in accordance with your specific verbal direction during the presubmission meeting, in that the permissible use sites are consistent with those determined to be eligible for reregistration in the 1997 RED and approximate the approved label for the now cancelled EPA Reg. No. 1812-424. However, these differences are not such that they would affect a determination of substantial similarity as defined in FIFRA Section 3(c)(3)(B)(i)(I).

Enclosed please find:

Application form 8570-1

Confidential Statement of Formula (Form 8570-4)

Data matrix forms for EPA and public use (Form 8570-35)

Transmittal bibliography

Three (3) copies of each submitted study

Five (5) copies of the proposed label

---

CONSULTANTS TO SUCCESS<sup>SM</sup>

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.



Letter to Jim Tompkins, October 16, 2003, page 2

Please note that we are relying upon the selective cite all method to satisfy data requirements that have not been satisfied by data submitted by Sinon Corporation. Applicable data requirements and determination of acceptable studies is based on the Paraquat Dichloride Reregistration Eligibility Document.

A Certification With Respect to Citation of Data (EPA Form 8570-34) is not included with this letter. A notification as required by 40 CFR §152.93 has been provided to the data submitter(s). Please process this application and notify me when the review is complete. If upon completion of the review the Agency is prepared to issue a registration, the Certification With Respect to Citation of Data will be filed.

Sinon is requesting a waiver from the requirements to assess the stability to metal and metal ions under OPPTS 830.6313, as the product is packaged, stored, and shipped in high density polyethylene and is not in contact with metals or metal ions. The submitted study meets the requirements for stability to normal and elevated temperatures under OPPTS 830.6313.

Please do not hesitate to call me immediately if there are any questions or if anything further is needed.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Anne Brown".

Elizabeth Anne Brown, Ph.D.

cc: Sinon Corporation

N/FT

# TRANSMITTAL DOCUMENT

## Submitter

Sinon Corporation

Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

\*ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

\*ChemReg International, LLC is the authorized representative for Sinon Corporation

## Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")  
Paraquat Technical Concentrate 70552-x

Transmittal Date  
October 16, 2003

## Submitted Studies

|             | MRID |                                                                                                                                                                                                       |
|-------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ----        |      | Administrative Materials                                                                                                                                                                              |
| Document 1: |      | Hauswirth, J.W. Sept. 12, 2003. Paraquat Technical. Product Identity, Composition, and Analysis (Group A). Report No. Sinon-Paraquat-A. 187 pages. <i>Contains Confidential Business Information.</i> |
| Document 2: |      | Hauswirth, J.W. Oct. 14, 2003. Paraquat Technical. Physical and Chemical Properties (Group B). Report No. Sinon-Paraquat-B. 203 pages.                                                                |
| Document 3: |      | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Acute Dermal Toxicity (Limit) Tests in Rats. Report No. Inversek Project Number 501197. 25 pages.                                             |
| Document 4: |      | Anderson, B.T.. June 12, 2002. Paraquat Technical. Acute Inhalation Toxicity in Rats. Report No. Inversek Project Number 661855. 37 pages.                                                            |
| Document 5: |      | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Acute Eye Irritation in Rabbits. Report No. Inversek Project Number 501218. 25 pages.                                                         |
| Document 6: |      | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Acute Dermal Irritation Test in Rabbits. Report No. Inversek Project Number 501202. 23 pages.                                                 |

## TRANSMITTAL DOCUMENT, Continued

|             |  |                                                                                                                                                                                          |
|-------------|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Document 7: |  | Hutchinson, A.K. February 12, 2002. Paraquat Technical. Buehler<br>Test in Guinea Pigs for Delayed Skin Sensitization Potential.<br>Report No. Inversek Project Number 501223. 32 pages. |
|-------------|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Company Official

*Judith W. Hauswirth*

Company Name:

ChemReg International, LLC, Authorized Agent for Sinon Corporation

Company Contact:

Judy W. Hauswirth

Phone Number:

703-492-1788



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

|                                                                                                                                                                                                                 |                                                                                                                                                                                                                        |                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| 1. Company/Product Number<br>70552- <del>F</del> <b>R</b>                                                                                                                                                       | 2. EPA Product Manager<br>Jim Tompkins                                                                                                                                                                                 | 3. Proposed Classification<br><input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Paraquat Technical Concentrate                                                                                                                                                     | PM #<br>25                                                                                                                                                                                                             |                                                                                                            |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Sinon Corporation<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC<br><input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:<br>EPA Reg No. <u>100-1067</u><br>Product Name <u>Paraquat Concentrate ES</u> |                                                                                                            |

## Section - II

|                                                                                |                                                                              |
|--------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| <input type="checkbox"/> Amendment - Explain below                             | <input type="checkbox"/> Final printed labels in response to                 |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input checked="" type="checkbox"/> Agency letter dated "Me Too" Application |
| <input type="checkbox"/> Notification - Explain below                          | <input type="checkbox"/> Other - Explain below                               |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

## Section III

|                                                                                                                         |                                                                                          |                                                                                                                                                                      |                       |                                                                                                                                           |                                                |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| 1. Material This Product Will be Packaged in:                                                                           |                                                                                          |                                                                                                                                                                      |                       | 2. Type of Container                                                                                                                      |                                                |
| Child-Resistant Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No                     | Unit Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No                                                                    |                       | <input type="checkbox"/> Metal                                                                                                            | <input checked="" type="checkbox"/> Plastic    |
| *Certification must be submitted                                                                                        |                                                                                          |                                                                                                                                                                      |                       | <input type="checkbox"/> Glass                                                                                                            | <input type="checkbox"/> Paper                 |
|                                                                                                                         | If "Yes" Unit Packaging wgt.                                                             | No. per container                                                                                                                                                    | If "Yes" Package wgt. | No. per container                                                                                                                         | <input type="checkbox"/> Other (Specify) _____ |
| 3. Location of Net Contents Information<br><input checked="" type="checkbox"/> Label <input type="checkbox"/> Container |                                                                                          | 4. Size(s) Retail Container<br>60 gallon HDPE                                                                                                                        |                       | 5. Location of label directions<br><input checked="" type="checkbox"/> On Label<br><input type="checkbox"/> On Label accompanying product |                                                |
| 6. Manner in Which Label is Affixed to Product                                                                          |                                                                                          | <input type="checkbox"/> Lithograph<br><input checked="" type="checkbox"/> Paper glued<br><input type="checkbox"/> Stenciled<br><input type="checkbox"/> Other _____ |                       |                                                                                                                                           |                                                |

## Section IV

|                                                                                                                                                                                                                                                                             |                                                          |                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|-------------------------------------------------------------|-----------------------------------------------|
| 1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)                                                                                                                              |                                                          |                                                             |                                               |
| Name<br>Elizabeth Anne Brown                                                                                                                                                                                                                                                | Title<br>Authorized Agent,<br>ChemReg International, LLC | Telephone No. (Include Area Code)<br>703-492-7905           |                                               |
| Certification<br>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. |                                                          |                                                             | 6. Date Application Received<br><br>(Stamped) |
| 2. Signature<br><i>Elizabeth Anne Brown</i>                                                                                                                                                                                                                                 |                                                          | 3. Title<br>Authorized Agent,<br>ChemReg International, LLC |                                               |
| 4. Typed Name<br>Elizabeth Anne Brown                                                                                                                                                                                                                                       |                                                          | 5. Date<br>10/16/2003                                       |                                               |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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**DATA MATRIX**

|                                                                                                                                       |                          |                                         |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 1 of 7                             |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          | Product: Paraquat Technical Concentrate |
| Ingredient: paraquat dichloride                                                                                                       |                          |                                         |

| Guideline Reference Number | Guideline Study Name                          | MRID Number | Submitter   | Status | Note       |
|----------------------------|-----------------------------------------------|-------------|-------------|--------|------------|
| 830.1550                   | Product identity and composition              |             | Sinon Corp. | Own    |            |
| 830.1600                   | Starting materials                            |             | Sinon Corp. | Own    |            |
| 830.1620                   | Method of manufacture                         |             | Sinon Corp. | Own    |            |
| 830.1670                   | Discussion of formation of impurities         |             | Sinon Corp. | Own    |            |
| 830.1700                   | Preliminary analysis                          |             | Sinon Corp. | Own    |            |
| 830.1750                   | Certification of limits                       |             | Sinon Corp. | Own    |            |
| 830.1800                   | Enforcement analytical method                 |             | Sinon Corp. | Own    |            |
| 830.6302                   | Color                                         |             | Sinon Corp. | Own    |            |
| 830.6303                   | Physical state                                |             | Sinon Corp. | Own    |            |
| 830.6304                   | Odor                                          |             | Sinon Corp. | Own    |            |
| 830.6313                   | Stability to normal and elevated temperatures |             | Sinon Corp. | Own    |            |
| 830.6314                   | Oxidation/reduction                           |             | Sinon Corp. | Own    | NA per RED |
| 830.6315                   | Flammability                                  |             | Sinon Corp. | Own    | NA per RED |
| 830.6316                   | Explosibility                                 |             | Sinon Corp. | Own    | NA per RED |
| 830.6317                   | Storage stability                             |             | Sinon Corp. | Own    | NA per RED |
| 830.6319                   | Miscibility                                   |             | Sinon Corp. | Own    | NA per RED |
| 830.6320                   | Corrosion characteristics                     |             | Sinon Corp. | Own    | NA per RED |
| 830.6321                   | Dielectric breakdown voltage                  |             | Sinon Corp. | Own    | NA per RED |
| 830.7000                   | pH                                            |             | Sinon Corp. | Own    |            |
| 830.7050                   | UV/visible absorption                         |             | Sinon Corp. | Own    |            |
| 830.7100                   | Viscosity                                     |             | Sinon Corp. | Own    |            |
| 830.7200                   | Melting point                                 |             | Sinon Corp. | Own    | NA per RED |

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|



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## DATA MATRIX

|                                                                                                                                       |                          |             |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 2 of 7 |
| Product: Paraquat Technical Concentrate                                                                                               |                          |             |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          |             |
| Ingredient: paraquat dichloride                                                                                                       |                          |             |

| Guideline Reference Number | Guideline Study Name       | MRID Number         | Submitter          | Status | Note       |
|----------------------------|----------------------------|---------------------|--------------------|--------|------------|
| 830.7220                   | Boiling point              |                     | Sinon Corp.        | Own    | NA per RED |
| 830.7300                   | Density                    |                     | Sinon Corp.        | Own    |            |
| 830.7370                   | Dissociation constant      |                     | Sinon Corp.        | Own    |            |
| 830.7550                   | Partition coefficient      |                     | Sinon Corp.        | Own    |            |
| 830.7840                   | Solubility                 |                     | Sinon Corp.        | Own    |            |
| 830.7950                   | Vapor pressure             |                     | Sinon Corp.        | Own    |            |
| 870.1100                   | Acute oral toxicity        | 43685001            | Zeneca             | Pay    |            |
| 870.1200                   | Acute dermal toxicity      |                     | Sinon Corp.        | Own    |            |
| 870.1300                   | Acute inhalation toxicity  |                     | Sinon Corp.        | Own    |            |
| 870.2400                   | Eye irritation             |                     | Sinon Corp.        | Own    |            |
| 870.2500                   | Dermal irritation          |                     | Sinon Corp.        | Own    |            |
| 870.2600                   | Dermal sensitization       |                     | Sinon Corp.        | Own    |            |
| 870.3150                   | 90-day feeding non-rodent  | 72416               | Scotts Co.         | Old    |            |
| 870.3200                   | 21-day dermal toxicity     | 156313              | Scotts Co.         | Old    |            |
| 870.3465                   | 90-day inhalation - rodent | 138637,<br>40218001 | Scotts Co., Zeneca | Old    |            |
| 870.4100                   | Chronic feeding rodent     | 138637,<br>40218001 | Scotts Co., Zeneca | Old    |            |
| 870.4100                   | Chronic feeding nonrodent  | 132474              | Scotts Co.         | Old    |            |

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|



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## DATA MATRIX

|                                                                                                                                       |                          |             |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 3 of 7 |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          |             |
| Product: Paraquat Technical Concentrate                                                                                               |                          |             |
| Ingredient: paraquat dichloride                                                                                                       |                          |             |

| Guideline Reference Number | Guideline Study Name            | MRID Number                                                                        | Submitter      | Status   | Note |
|----------------------------|---------------------------------|------------------------------------------------------------------------------------|----------------|----------|------|
| 870.4200                   | Carcinogenicity - rat           | 138637,<br>152332,<br>40183501,<br>40202401,<br>40202402,<br>41317401,<br>40218001 | Zeneca         | Old/pay  |      |
| 870.4200                   | Carcinogenicity - mouse         | 87924,<br>40202403                                                                 | Scotts, Zeneca | Old/publ |      |
| 870.3700                   | Developmental toxicity - rat    | 113714                                                                             | Scotts         | Old      |      |
| 870.3700                   | Developmental toxicity - rabbit | 96338                                                                              | Scotts         | Old      |      |
| 870.3800                   | 2-generation reproduction - rat | 126783                                                                             | Scotts         | Old      |      |
| 870.5100                   | Gene mutation (Ames test)       | 152690,<br>152691                                                                  | Scotts         | Old      |      |
| 84-2B                      | Structural chromosomal effects  | 73487, 152692,<br>40202404                                                         | Scotts, Zeneca | Old      |      |
| 84-4                       | Other genotoxic effects         | 15293, 100422,<br>152695,<br>40202405                                              | Scotts, Zeneca | Old      |      |
| 870.7485                   | General metabolism              | 28597, 35297,<br>28598, 55107,<br>28599, 126096                                    | Scotts         | Old      |      |

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|





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**DATA MATRIX**

|                                                                                                                                       |                                         |             |
|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol                | Page 4 of 7 |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC | Product: Paraquat Technical Concentrate |             |
| Ingredient: paraquat dichloride                                                                                                       |                                         |             |

| Guideline Reference Number | Guideline Study Name                | MRID Number                                        | Submitter                                            | Status | Note |
|----------------------------|-------------------------------------|----------------------------------------------------|------------------------------------------------------|--------|------|
| 870.7600                   | Dermal penetration                  | 126096,<br>126097,<br>126098,<br>126099,<br>153439 | Scotts                                               | Old    |      |
| 850.2100                   | Acute avian oral - quail/duck       | 29001, 102038,<br>160000,<br>5008363               | Scotts Co, Pesticon Systems, US F&WS,<br>Bayer Corp. | Old    |      |
| 850.2200                   | Avian dietary - quail               | 22923                                              | US F&WS                                              | Publ   |      |
| 850.2200                   | Avian dietary - duck                | 22923                                              | US F&WS                                              | Publ   |      |
| 850.2300                   | Avian reproduction quail            | 110453,<br>110454                                  | Scotts Co.                                           | Old    |      |
| 850.2300                   | Avian reproduction duck             | 110455                                             | Scotts Co.                                           | Old    |      |
| 850.1075                   | Fish toxicity bluegill              | 40098001,<br>162737                                | Syngenta                                             | Old    |      |
| 850.1075                   | Fish toxicity rainbow trout         | 40098001,<br>162736,<br>162738                     | Syngenta, Zeneca                                     | Old    |      |
| 850.1010                   | Invertebrate toxicity               | 40098001,<br>114473,<br>GS262-028                  | Syngenta, Zeneca                                     | Old    | Fn 1 |
| 850.4225                   | Seed germination/seedling emergence | 42639601                                           | Zeneca                                               | Pay    |      |
| 850.4250                   | Vegetative vigor                    | 42601001                                           | Zeneca                                               | Pay    |      |

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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## DATA MATRIX

|                                                                                                                                       |                                         |             |
|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./File Symbol                 | Page 5 of 7 |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC | Product: Paraquat Technical Concentrate |             |
| Ingredient: paraquat dichloride                                                                                                       |                                         |             |

| Guideline Reference Number | Guideline Study Name                  | MRID Number                                                  | Submitter                       | Status | Note         |
|----------------------------|---------------------------------------|--------------------------------------------------------------|---------------------------------|--------|--------------|
| 850.4400                   | Aquatic plant growth                  | 42601002,<br>42601003,<br>42601004,<br>42601005,<br>42601006 | Zeneca                          | Pay    |              |
| 850.3020                   | Honey bee acute contact               | 5001991,<br>28772, 111488                                    | Dow Chemical, unknown submitter | Old    |              |
| 875.2200                   | Soil residue dissipation              | Waived                                                       |                                 |        | Waived - RED |
| 875.2400                   | Dermal passive dosimetry exposure     | Waived                                                       |                                 |        | Waived - RED |
| 875.2500                   | Inhalation passive dosimetry exposure | Waived                                                       |                                 |        | Waived - RED |
| 161-1                      | Hydrolysis                            | Upton                                                        |                                 |        | Fn 2         |
| 161-2                      | Photodegradation - water              | 40562301                                                     | Zeneca                          | Old    |              |
| 161-3                      | Photodegradation - soil               | Pack                                                         |                                 |        | Fn 2         |
| 162-1                      | Aerobic soil metabolism               | 41319301                                                     | Zeneca                          | Pay    |              |
| 162-2                      | Anaerobic soil metabolism             | 41319302                                                     | Zeneca                          | Pay    |              |
| 163-1                      | Leaching/adsorption - desorption      | 40762701                                                     | Zeneca                          | Old    |              |
| 164-1                      | Terrestrial field dissipation         | 41352101,<br>41352102                                        | Zeneca                          | Pay    |              |
| 164-5                      | Long term soil dissipation            | 42802101,<br>42802102,<br>42738701,<br>42738702              | Zeneca                          | Pay    |              |
| 165-1                      | Confined rotational crop              | 41645601                                                     | Zeneca                          | Pay    |              |

Signature

*Judith W. Hauswirth*

Name and Title  
Judith W. Hauswirth, Ph.D.  
ChemReg International  
Authorized Agent for Sinon Corporation

Date  
October 14,  
2003



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## DATA MATRIX

|                                                                                                                                       |                          |                                         |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol | Page 6 of 7                             |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC |                          | Product: Paraquat Technical Concentrate |
| Ingredient: paraquat dichloride                                                                                                       |                          |                                         |

| Guideline Reference Number | Guideline Study Name                | MRID Number | Submitter                                | Status          | Note         |
|----------------------------|-------------------------------------|-------------|------------------------------------------|-----------------|--------------|
| 165-5                      | Bioaccumulation - aquatic nontarget | Waived      |                                          |                 | Waived - RED |
| 840.1100                   | Droplet size spectrum               | Cite-all    | Spray Drift Task Force                   | Pay             |              |
| 840.1200                   | Drift field evaluation              | Cite-all    | Spray Drift Task Force                   | Pay             |              |
| 860.1300                   | Nature of residue - plants          | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
| 860.1300                   | Nature of residue - livestock       | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
| 860.1340                   | Residue analytical methods          | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
| 860.1360                   | Multiresidue method                 | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
| 860.1380                   | Storage stability of residues       | Cite-all    | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
| 860.1500                   | Crop field trials                   | Cite-all    | Zeneca, Scotts Co., IR-4, Shell Chemical | Pay/old/<br>pub |              |
| 860.1520                   | Processed food/feed                 | Cite-all    | Zeneca                                   | Pay/old/<br>pub |              |
| Special                    | Endangered Species                  | Cite-all    | Endangered Species Task Force            | Pay             |              |

NOTE: Guidelines listed but shown as "Not required" in RED, Appendix B are not included here as the guideline has been determined to be not applicable

(1) as referenced in RED, Appendix B. C.

GS0262-028: US EPA (1579) 48-hour EC50: Paraquat dichloride 29.1%: Daphnia magna: Test 2431. Unpublished report prepared by Terrestrial Aquatic Biology Laboratory. 1 p

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|



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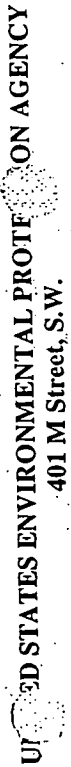
**DATA MATRIX**

|                                                                                                                                       |                                         |             |
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| Date: October 14, 2003                                                                                                                | EPA Reg No./File Symbol                 | Page 7 of 7 |
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| Ingredient: paraquat dichloride                                                                                                       |                                         |             |

(2) as referenced in RED, Appendix B: "Guideline fulfilled: no MRID #'s for this study - review dated 2/14/85"

(214)

|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
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| Ingredient: paraquat dichloride                                                                                                       |                                         |             |

[illegible]

Signature

Judith W. Hauswirth

**Name and Title**  
Judith W. Hauswirth, Ph.D.  
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Authorized Agent for Simon Corporation

Date  
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2003

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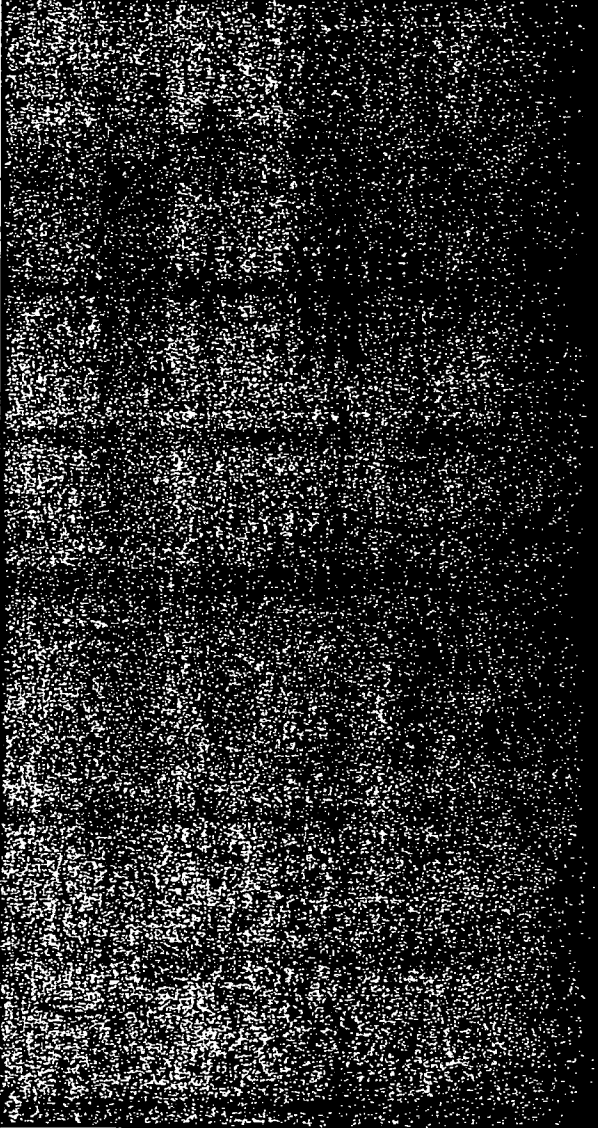
Page 2 of 7

Applicant's/Registrant's Name and Address:

Sinon Corp.  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

Product: Paraquat Technical Concentrate

Ingredient: paraquat dichloride

| Guideline Reference Number | Guideline Study Name                                                                | MRID Number | Submitter          | Status | Note       |
|----------------------------|-------------------------------------------------------------------------------------|-------------|--------------------|--------|------------|
| 216                        |  |             | Sinon Corp.        | Own    | NA per RED |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Zeneca             | Pay    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Sinon Corp.        | Own    |            |
|                            |                                                                                     |             | Scotts Co.         | Old    |            |
|                            |                                                                                     |             | Scotts Co.         | Old    |            |
|                            |                                                                                     |             | Scotts Co., Zeneca | Old    |            |
|                            |                                                                                     |             | Scotts Co., Zeneca | Old    |            |
|                            |                                                                                     |             | Scotts Co.         | Old    |            |

Signature

*Judith W. Hauswirth*

Name and Title

Judith W. Hauswirth, Ph.D.  
ChemReg International  
Authorized Agent for Sinon CorporationDate  
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2003

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## DATA MATRIX

|                                                                                                                                       |                                         |             |
|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------|
| Date: October 14, 2003                                                                                                                | EPA Reg No./ File Symbol                | Page 3 of 7 |
| Applicant's/Registrant's Name and Address:<br>Sinon Corp.<br>111, Chuang-Shan Road<br>Ta-Tu Hsiang, Taichung Hsien 432<br>Taiwan, ROC | Product: Paraquat Technical Concentrate |             |
| Ingredient: paraquat dichloride                                                                                                       |                                         |             |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter      | Status   | Note |
|----------------------------|----------------------|-------------|----------------|----------|------|
|                            |                      |             | Zeneca         | Old/pay  |      |
|                            |                      |             | Scotts, Zeneca | Old/publ |      |
|                            |                      |             | Scotts         | Old      |      |
|                            |                      |             | Scotts         | Old      |      |
|                            |                      |             | Scotts         | Old      |      |
|                            |                      |             | Scotts         | Old      |      |
|                            |                      |             | Scotts, Zeneca | Old      |      |
|                            |                      |             | Scotts, Zeneca | Old      |      |
|                            |                      |             | Scotts         | Old      |      |
|                            |                      |             | Scotts         | Old      |      |

|                                         |                                                                                                                 |                          |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14, 2003 |
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| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter                                           | Status | Note |
|----------------------------|----------------------|-------------|-----------------------------------------------------|--------|------|
|                            |                      |             | Scotts                                              | Old    |      |
|                            |                      |             | Scotts Co, Pestcon Systems, US F&WS,<br>Bayer Corp. | Old    |      |
|                            |                      |             | US F&WS                                             | Publ   |      |
|                            |                      |             | US F&WS                                             | Publ   |      |
|                            |                      |             | Scotts Co.                                          | Old    |      |
|                            |                      |             | Scotts Co.                                          | Old    |      |
|                            |                      |             | Syngenta                                            | Old    |      |
|                            |                      |             | Syngenta, Zeneca                                    | Old    |      |
|                            |                      |             | Syngenta, Zeneca                                    | Old    | Fn I |
|                            |                      |             | Zeneca                                              | Pay    |      |
|                            |                      |             | Zeneca                                              | Pay    |      |

Signature

*Judith W. Hauswirth*

Name and Title

Judith W. Hauswirth, Ph.D.  
ChemReg International  
Authorized Agent for Siron Corporation

Date

October 14,  
2003





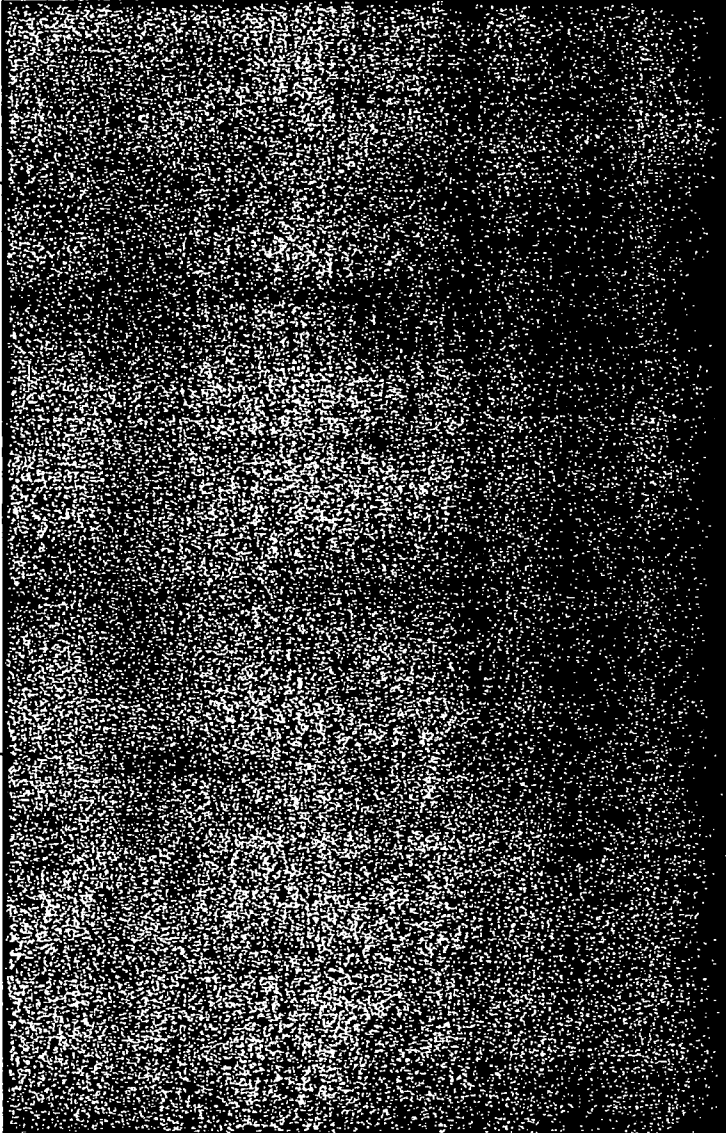
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| Guideline Reference Number                                                          | Guideline Study Name | MRID Number | Submitter                       | Status | Note         |
|-------------------------------------------------------------------------------------|----------------------|-------------|---------------------------------|--------|--------------|
|  |                      |             | Zeneca                          | Pay    |              |
|                                                                                     |                      |             | Dow Chemical, unknown submitter | Old    |              |
|                                                                                     |                      |             |                                 |        | Waived - RED |
|                                                                                     |                      |             |                                 |        | Waived - RED |
|                                                                                     |                      |             |                                 |        | Waived - RED |
|                                                                                     |                      |             |                                 |        | Fn 2         |
|                                                                                     |                      |             | Zeneca                          | Old    | Fn 2         |
|                                                                                     |                      |             | Zeneca                          | Pay    |              |
|                                                                                     |                      |             | Zeneca                          | Pay    |              |
|                                                                                     |                      |             | Zeneca                          | Old    |              |
|                                                                                     |                      |             | Zeneca                          | Pay    |              |
|                                                                                     |                      |             | Zeneca                          | Pay    |              |
|                                                                                     |                      |             | Zeneca                          | Pay    |              |
|                                                                                     |                      |             | Zeneca                          | Pay    |              |

|                                         |                                                                                                                 |                             |
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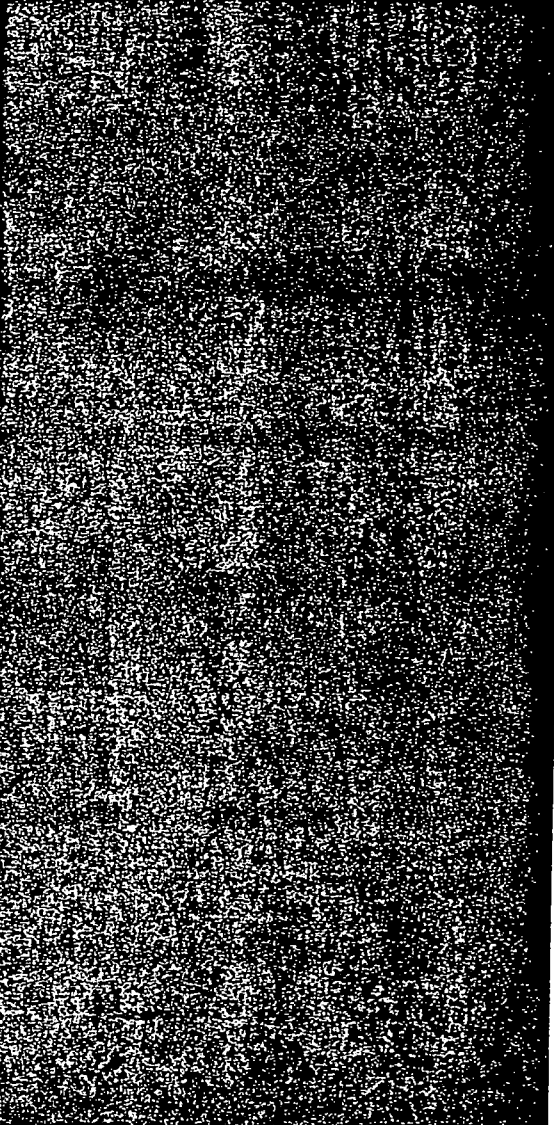
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| Guideline Reference Number | Guideline Study Name                                                                | MRID Number | Submitter                                | Status          | Note         |
|----------------------------|-------------------------------------------------------------------------------------|-------------|------------------------------------------|-----------------|--------------|
| 220                        |  |             | Spray Drift Task Force                   | Pay             | Waived - RED |
|                            |                                                                                     |             | Spray Drift Task Force                   | Pay             |              |
|                            |                                                                                     |             | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
|                            |                                                                                     |             | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
|                            |                                                                                     |             | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
|                            |                                                                                     |             | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
|                            |                                                                                     |             | Zeneca, Scotts Co.                       | Pay/old/<br>pub |              |
|                            |                                                                                     |             | Zeneca, Scotts Co., IR-4, Shell Chemical | Pay/old/<br>pub |              |
|                            |                                                                                     |             | Zeneca                                   | Pay/old/<br>pub |              |
|                            |                                                                                     |             | Endangered Species Task Force            | Pay             |              |

NOTE: Guidelines listed but shown as "Not required" in RED, Appendix B are not included here as the guideline has been determined to be not applicable (1) as referenced in RED, Appendix B, C:

GS0262-028. US EPA (1979) 48-hour EC50: Paraquat dichloride 29.1%. Daphnia magna: Test 2431. Unpublished report prepared by Terrestrial Aquatic Biology Laboratory. 1 p

|                                         |                                                                                                                 |                             |
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| Ingredient: paraquat dichloride                                                                                                       |                          |                                         |

(2) as referenced in RED, Appendix B: "Guideline fulfilled; no MRID #'s for this study - review dated 2/14/85

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|                                         |                                                                                                                 |                             |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|
| Signature<br><i>Judith W. Hauswirth</i> | Name and Title<br>Judith W. Hauswirth, Ph.D.<br>ChemReg International<br>Authorized Agent for Sinon Corporation | Date<br>October 14,<br>2003 |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------|

## Paraquat Technical Concentrate

For Formulation of Paraquat Herbicide Products Only

### ACTIVE INGREDIENT

Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride).....46.2%

INERT INGREDIENTS.....53.8%

TOTAL.....100.0%

Contains 3 pounds paraquat cation per gallon

EPA Reg. No. 70552-x

EPA Establishment No. 70552-TWN-001

**KEEP OUT OF REACH OF CHILDREN**

**DANGER – PELIGRO**



**POISON**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• Call Poison Control Center or doctor immediately for treatment advice</li><li>• Have person sip a glass of water if able to swallow</li><li>• Do not induce vomiting unless told to by a poison control center or doctor</li><li>• Do not give anything by mouth to an unconscious person</li></ul> |
| If inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Move person to fresh air</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                         |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                            |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"><li>• Take off contaminated clothing</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                                                                                 |
| HOTLINE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                             |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                             |
| NOTE TO PHYSICIANS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                             |
| CALL CHEMTREC 1-800-424-9300 at any hour to obtain toxicology and medical management consultation and paraquat analyses. Prompt treatment is essential and must be initiated immediately before signs and symptoms appear. Symptoms are prolonged and painful and may be delayed for days after swallowing. Treatment may include binding paraquat in the gut with suspensions of clay or charcoal; and/or removal of paraquat from the blood by prolonged charcoal hemoperfusion or continuous hemodialysis. Probable mucosal damage may contraindicate the use of gastric lavage. |                                                                                                                                                                                                                                                                                                                                             |

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### DANGER – POISON



Fatal if inhaled. May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe spray mist. Do not inhale contaminated dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
  - Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)
  - Full face shield
  - Chemical-resistant gloves, Category A
  - Apron and waterproof footwear
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

### ENVIRONMENTAL HAZARDS

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

### PHYSICAL AND CHEMICAL HAZARD

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

### SPILLAGE DURING TRANSPORT

**Emergency Action:** Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

KEEP PUBLIC AND ANIMALS away from area. MARK ROADS AND WARN OTHER ROAD USERS. WEAR face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into a herbicide for the following uses:

- (1) Terrestrial Food: **Alfalfa, Almond, Asparagus, Beans Dry** (Adzuki beans, Asparagus bean, Black bean, Broad bean, Field bean, Garbanzo bean, White sweet lupine, White lupine, Kidney bean, Lablab bean, Lima bean, Fava bean, Mung bean, Navy bean, Pinto bean, Rice bean, Snap bean, Tepary bean, Urd bean, Waxbean, Blackeyed pea, Chickpea, Cowpea, Crowder pea, Southern pea, Catjang, Guar), **Berries** (Blackberries, Blueberries, Boysenberries, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry), **Cassavas, Clover, Legumes** (Venvet bean, Lespedeza, Lupine, Sainfoin, Trefoil, Vetch, Crown Vetch, Milk Vetch), **Corn** (Pop, Field, and Sweet), **Cotton, Grain lupine, Grasses** (pasture and range), **Guava, Hops, Lentil, Mint** (Peppermint, Spearmint), **Onions, Garlic, Passion fruit, Pastures, Peanuts, Pigeon Peas, Pineapple, Potato, Rice, Safflower, Small fruits, Small grains** (Barley, Wheat), **Sorghum** (grain), **Strawberries, Soybeans, Sugar beets, Sugarcane, Sunflower, Sweet lupine, Taniers, Taro, Trees and Vines** (Acerola, Apple, Apricot, Avocado, Banana, Beechnut, Brazil nut, Butternut, Calamondin, Cashew, Cherry, Chestnut, Chinquapin, Citrus Citron, Coffee, Crabapple, Fig, Filbert, Grape, Grapefruit, Hickory nut, Kiwi fruit, Jumquat, Lemon, Lime, Loquat, Macadamia nut, Mandarin, Mayhaw, Nectarines, Olive, Orange (sweet and sour), Papaya, Peach, Pear (oriental), Pecan, Pistachio, Plum, Prune, Pummelo, Quince, Satsuma mandarin, Walnut, Shade and Ornamental trees (such as Arbovitae, Ash, Elm, Oak, Pine, etc.)), **Tylon, Vegetables** (Broccoli, Brussels sprouts, Cabbage, Cantaloupe, Carrot, Cauliflower, Cavalo, Chayote fruit, Chinese cabbage, Chinese wasgourd, Citron melon, Collard, Cucumber, Eggplant, Gherkin, Gourd (edible), Ground cherry, *Momordica* spp., Kale, Kohlrabi, Lettuce, Mizune, Musk melon, Mustard greens, Mustard spinach, Peas, Pepino, Pepper, Pumpkin, Rape greens, Squash, Sweet corn, Tomatillo, Tomato, Turnip, Watermelon, Eggplant, Pepper, Chili pepper, Rubarb), **Yams**.

Terrestrial Nonfood: Conservation Compliance Lands, Conservation Reserve Lands, Federal Set-Aside Lands, Grasses grown for seed, resin soaking (pines), Tree plantation establishment.

- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

#### WARRANTY STATEMENT

SINON CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by Buyer and User. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this product. SINON CORP. makes no warranties of merchantability or of fitness for a particular purpose nor for any other expressed or implied warranty except as stated above.

Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 10-14-2003. NOT EPA APPROVED

## Paraquat Technical Concentrate

For Formulation of Paraquat Herbicide Products Only

### ACTIVE INGREDIENT

Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride).....46.2%

INERT INGREDIENTS.....53.8%

TOTAL.....100.0%

Contains 3 pounds paraquat cation per gallon

EPA Reg. No. 70552-x

EPA Establishment No. 70552-TWN-001

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER – PELIGRO**



**POISON**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• Call Poison Control Center or doctor immediately for treatment advice</li><li>• Have person sip a glass of water if able to swallow</li><li>• Do not induce vomiting unless told to by a poison control center or doctor</li><li>• Do not give anything by mouth to an unconscious person</li></ul> |
| If inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Move person to fresh air</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                         |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                            |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"><li>• Take off contaminated clothing</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                                                                                 |
| HOTLINE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                             |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                             |
| NOTE TO PHYSICIANS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                             |
| CALL CHEMTREC 1-800-424-9300 at any hour to obtain toxicology and medical management consultation and paraquat analyses. Prompt treatment is essential and must be initiated immediately before signs and symptoms appear. Symptoms are prolonged and painful and may be delayed for days after swallowing. Treatment may include binding paraquat in the gut with suspensions of clay or charcoal; and/or removal of paraquat from the blood by prolonged charcoal hemoperfusion or continuous hemodialysis. Probable mucosal damage may contraindicate the use of gastric lavage. |                                                                                                                                                                                                                                                                                                                                             |

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## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### DANGER – POISON



Fatal if inhaled. May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe spray mist. Do not inhale contaminated dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
  - Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)
  - Full face shield
  - Chemical-resistant gloves, Category A
  - Apron and waterproof footwear
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

### ENVIRONMENTAL HAZARDS

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

### PHYSICAL AND CHEMICAL HAZARD

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

### SPILLAGE DURING TRANSPORT

**Emergency Action:** Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

**KEEP PUBLIC AND ANIMALS** away from area. **MARK ROADS AND WARN OTHER ROAD USERS.**  
**WEAR** face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

## DIRECTIONS FOR USE

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**Terrestrial Nonfood:** Conservation Compliance Lands, Conservation Reserve Lands, Federal Set-Aside Lands, Grasses grown for seed, resin soaking (pines), Tree plantation establishment.

- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

#### WARRANTY STATEMENT

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Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 10-14-2003. NOT EPA APPROVED

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## Paraquat Technical Concentrate

### For Formulation of Paraquat Herbicide Products Only

#### ACTIVE INGREDIENT

Paraquat dichloride (1,1'-dimethyl, 4,4'-bipyridinium dichloride).....46.2%

INERT INGREDIENTS.....53.8%

TOTAL.....100.0%

Contains 3 pounds paraquat cation per gallon

EPA Reg. No. 70552-x

EPA Establishment No. 70552-TWN-001

### KEEP OUT OF REACH OF CHILDREN

### DANGER - PELIGRO



### POISON

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• Call Poison Control Center or doctor immediately for treatment advice</li><li>• Have person sip a glass of water if able to swallow</li><li>• Do not induce vomiting unless told to by a poison control center or doctor</li><li>• Do not give anything by mouth to an unconscious person</li></ul> |
| If inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Move person to fresh air</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                         |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                            |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"><li>• Take off contaminated clothing</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                                                                                 |
| HOTLINE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                             |
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| NOTE TO PHYSICIANS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                             |
| CALL CHEMTREC 1-800-424-9300 at any hour to obtain toxicology and medical management consultation and paraquat analyses. Prompt treatment is essential and must be initiated immediately before signs and symptoms appear. Symptoms are prolonged and painful and may be delayed for days after swallowing. Treatment may include binding paraquat in the gut with suspensions of clay or charcoal; and/or removal of paraquat from the blood by prolonged charcoal hemoperfusion or continuous hemodialysis. Probable mucosal damage may contraindicate the use of gastric lavage. |                                                                                                                                                                                                                                                                                                                                             |

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### DANGER – POISON



Fatal if inhaled. May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe spray mist. Do not inhale contaminated dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
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  - Full face shield
  - Chemical-resistant gloves, Category A
  - Apron and waterproof footwear
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

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### PHYSICAL AND CHEMICAL HAZARD

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

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Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

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- NEVER PUT INTO FOOD, DRINK OR OTHER CONTAINERS
- IF SWALLOWED, TAKE IMMEDIATE ACTION AS PRESCRIBED IN FIRST AID STATEMENT. SYMPTOMS ARE PROLONGED AND PAINFUL.

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If swallowed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• Call Poison Control Center or doctor immediately for treatment advice</li><li>• Have person sip a glass of water if able to swallow</li><li>• Do not induce vomiting unless told to by a poison control center or doctor</li><li>• Do not give anything by mouth to an unconscious person</li></ul> |
| If inhaled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Move person to fresh air</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                         |
| If in eyes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                            |
| If on skin or clothing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"><li>• Take off contaminated clothing</li><li>• Rinse skin immediately with plenty of water for 15 to 20 minutes</li><li>• Call Poison Control Center or doctor immediately for treatment advice</li></ul>                                                                                                 |
| HOTLINE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                             |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies involving this product, call CHEMTREC 1-800-424-9300. For chemical emergency: spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300.                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                             |
| NOTE TO PHYSICIANS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                             |
| CALL CHEMTREC 1-800-424-9300 at any hour to obtain toxicology and medical management consultation and paraquat analyses. Prompt treatment is essential and must be initiated immediately before signs and symptoms appear. Symptoms are prolonged and painful and may be delayed for days after swallowing. Treatment may include binding paraquat in the gut with suspensions of clay or charcoal; and/or removal of paraquat from the blood by prolonged charcoal hemoperfusion or continuous hemodialysis. Probable mucosal damage may contraindicate the use of gastric lavage. |                                                                                                                                                                                                                                                                                                                                             |

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## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### DANGER – POISON



Fatal if inhaled. May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe spray mist. Do not inhale contaminated dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

- When handling or mixing concentrate or when exposure to concentrate is possible, wear:
  - Dust/mist filtering NIOSH approved respirator with any R, P or HE filter
  - Protective clothing (disposable suit/coveralls or long-sleeved shirt and pants)
  - Full face shield
  - Chemical-resistant gloves, Category A
  - Apron and waterproof footwear
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- REMOVE contaminated clothing and wash separately from other laundry before reuse

**IMPORTANT:** The effect of swallowing paraquat concentrate is far more severe than that which usually results from skin contact or inhalation of contaminated plant dust. This product should not cause injury if used according to label instructions.

### ENVIRONMENTAL HAZARDS

This product is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

### PHYSICAL AND CHEMICAL HAZARD

This product reacts with aluminum to produce hydrogen gas which may form a highly combustible gas mixture. Do not mix or store in containers, tanks, or such systems made of aluminum or having aluminum fittings.

**EQUIPMENT/CONTAINER:** Flush all equipment with water after use each day. Paraquat is corrosive to aluminum. Aluminum equipment and aluminum structures that are exposed to solution or spillage should be flushed thoroughly with water immediately after use.

### SPILLAGE DURING TRANSPORT

**Emergency Action:** Notify police and fire departments immediately. For any spill, leak, fire, or exposure in the United States, call CHEMTREC 1-800-424-9300.

**KEEP PUBLIC AND ANIMALS** away from area. **MARK ROADS AND WARN OTHER ROAD USERS.** **WEAR** face shield, waterproof gloves, waterproof footwear, and long-sleeve shirt and long pants during decontamination operations.

Clean up spills as soon as possible. Cover spill with generous amount of clay or loam soil to absorb liquid, using a stiff broom to ensure intimate contact. Sweep onto shovel and transfer to plastic bag or other disposable container. Repeat operations until contaminated surfaces are dry. Finally, hose spill site with water, if feasible.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into a herbicide for the following uses:

- (1) Terrestrial Food: **Alfalfa, Almond, Asparagus, Beans Dry** (Adzuki beans, Asparagus bean, Black bean, Broad bean, Field bean, Garbanzo bean, White sweet lupine, White lupine, Kidney bean, Lablab bean, Lima bean, Fava bean, Mung bean, Navy bean, Pinto bean, Rice bean, Snap bean, Tepary bean, Urd bean, Waxbean, Blackeyed pea, Chickpea, Cowpea, Crowder pea, Southern pea, Catjang, Guar), **Berries** (Blackberries, Blueberries, Boysenberries, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry), **Cassavas, Clover, Legumes** (Venet bean, Lespedeza, Lupine, Sainfoin, Trefoil, Vetch, Crown Vetch, Milk Vetch), **Corn** (Pop, Field, and Sweet), **Cotton, Grain lupine, Grasses** (pasture and range), **Guava, Hops, Lentil, Mint** (Peppermint, Spearmint), **Onions, Garlic, Passion fruit, Pastures, Peanuts, Pigeon Peas, Pineapple, Potato, Rice, Safflower, Small fruits, Small grains** (Barley, Wheat), **Sorghum** (grain), **Strawberries, Soybeans, Sugar beets, Sugarcane, Sunflower, Sweet lupine, Taniers, Taro, Trees and Vines** (Acerola, Apple, Apricot, Avocado, Banana, Beechnut, Brazil nut, Butternut, Calamondin, Cashew, Cherry, Chestnut, Chinquapin, Citrus Citron, Coffee, Crabapple, Fig, Filbert, Grape, Grapefruit, Hickory nut, Kiwi fruit, Jumquat, Lemon, Lime, Loquat, Macadamia nut, Mandarin, Mayhaw, Nectarines, Olive, Orange (sweet and sour), Papaya, Peach, Pear (oriental), Pecan, Pistachio, Plum, Prune, Pummelo, Quince, Satsuma mandarin, Walnut, Shade and Ornamental trees (such as Arbovitae, Ash, Elm, Oak, Pine, etc.)), **Tylon, Vegetables** (Broccoli, Brussels sprouts, Cabbage, Cantaloupe, Carrot, Cauliflower, Cavalo, Chayote fruit, Chinese cabbage, Chinese wasgourd, Citron melon, Collard, Cucumber, Eggplant, Gherkin, Gourd (edible), Ground cherry, *Momordica* spp., Kale, Kohlrabi, Lettuce, Mizune, Musk melon, Mustard greens, Mustard spinach, Peas, Pepino, Pepper, Pumpkin, Rape greens, Squash, Sweet corn, Tomatillo, Tomato, Turnip, Watermelon, Eggplant, Pepper, Chili pepper, Rubarb), **Yams.**

Terrestrial Nonfood: Conservation Compliance Lands, Conservation Reserve Lands, Federal Set-Aside Lands, Grasses grown for seed, resin soaking (pines), Tree plantation establishment.

- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited.

**PESTICIDE STORAGE:** Store at temperatures above 32° F. Do not contaminate food, foodstuffs, or drinking water. Do not store next to feed or food, or transport in or on vehicles containing foodstuffs or feeds. For help with any spill, leak, fire or exposure involving this material, call CHEMTREC 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or dispose of by other procedures allowed by State and local authorities.

#### WARRANTY STATEMENT

SINON CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by Buyer and User. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this product. SINON CORP. makes no warranties of merchantability or of fitness for a particular purpose nor for any other expressed or implied warranty except as stated above.

Manufactured by:  
Sinon Corporation  
111, Chuang-Shan Road  
Ta-Tu Hsiang, Taichung Hsien 432  
Taiwan, ROC

DRAFT: 10-14-2003. NOT EPA APPROVED

REGISTRATION NO.

**Do Not Write Comments,  
Formula, or Parts of Formula  
on This Envelope**

It shall be unlawful-----for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States; Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

[illegible]

Registration File NO. 70552-1

Page \_\_\_\_\_ is not included in this copy.

Pages 239 through 242 are not included in this copy.

The material not included contains the following type of information:

- \_\_\_\_\_ Identity of product inert ingredients.
- \_\_\_\_\_ Identity of product impurities.
- \_\_\_\_\_ Description of the product manufacturing process.
- \_\_\_\_\_ Description of quality control procedures.
- \_\_\_\_\_ Identity of the source of product ingredients.
- \_\_\_\_\_ Sales or other commercial/financial information.
- \_\_\_\_\_ A draft product label.
- ☒ The product confidential statement of formula.
- \_\_\_\_\_ Information about a pending registration action.
- \_\_\_\_\_ FIFRA registration data.
- \_\_\_\_\_ The document is a duplicate of page(s) \_\_\_\_\_.
- \_\_\_\_\_ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

